S. Hrg. 99-222

NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT OF 1985

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

ON

S. 827

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO PROVIDE FOR THE COMPENSATION OF CHILDREN AND OTHERS WHO HAVE SUSTAINED VACCINE-RELATED INJURIES, AND FOR OTHER PURPOSES

JULY 18, 1985

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NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT OF 1985

THURSDAY, JULY 18, 1985

U.S. Senate,
Committee on Labor and Human Resources,
Washington, DC.

The committee met, pursuant to call, at 9:31 a.m., in room 430 of the Dirksen Senate Office Building, Senator Orrin G. Hatch (chairman), presiding.

Present: Senators Hatch, Hawkins, Thurmond, Stafford, Nickles, Kennedy, Pell, Dodd, and Kerry.

OPENING STATEMENT OF SENATOR HATCH

The Chairman. Today we are holding full Labor and Human Resources Committee hearings devoted to a public health problem of critical importance—improving our National Childhood Vaccine Program.

Coincidentally, this month marks the 100th anniversary of the date when Louis Pasteur injected an inactivated rabies virus into a 9-year-old child who had been bitten by a rabid dog. Thus began the modern era of disease prevention. Pasteur's injection of this vaccine was the culmination of years of painstaking and rigorous research. But his decision on that day in July was a judgment to use a method which had been successful in dogs and rabbits, but had never before been used in humans, and a judgment to use this method for a child who otherwise was almost certainly going to die.

At that moment in history, Pasteur demonstrated responsible health policy, coupled with compassion and concern for children—a combination which continues today to motivate us to maintain and improve our Childhood Immunization Program.

It is compassion which drives this legislative process; it is concern for children and their health that has stimulated development of three different legislative proposals designed to maintain and improve the most effective disease prevention effort ever launched.

I want to recognize the leadership of Senator Paula Hawkins of Florida on this issue, and her efforts to develop the first legislative proposal to address current problems associated with our National Childhood Immunization Program.

This issue is one to which Senator Hawkins and her staff have devoted an enormous amount of time and effort. Many hundreds of hours were spent in developing the proposal that Senator Hawkins and I introduced on April 2 of this year, and I am certain that many more hours of discussion and negotiation will follow this hearing.

Today's hearing includes witnesses with a broad range of viewpoints, and is a deliberate attempt to have before the committee a wide array of views on the pending legislation. We will use this testimony as true guidance and counsel, and we will work to achieve legislation that will assure an ongoing and safer immunization program. In addition, we will work to achieve a satisfactory resolution of compensation problems.

This is a complex and emotional issue. We must work together to resolve this issue, and our deliberations should be characterized by cooperation, understanding, respect, and compromise.

Let me lay out some of what I perceive to be the major and essential questions that need to be dealt with by the committee and the Congress. The issues I believe must be addressed are these—not necessarily in order of importance—vaccine safety, better education of parents and health care providers, improved reporting of vaccine-related side effects and adverse reactions, availability of vaccines, and, of course, compensation.

The question of the relative safety of vaccines has been raised particularly, although not exclusively, about the pertussis vaccine, one component of the DTP shots given routinely to children throughout the world. Numerous articles, studies, reports, and even a book have addressed this issue. A special HHS task force, established at the request of Senator Hawkins, looked particularly at pertussis vaccination. This chart illustrates some of the interest in this issue that has been generated worldwide.

In addition, unfortunately, there have been some serious allegations of concealed information and deliberate negligence. With respect to those charges, an organization called Advocates for a Safe Vaccine has put together a report on the subject of safety of pertussis vaccine, and requested to present testimony for this particular hearing. Without objection, testimony submitted by this group will be included in our hearing record.

Every effort must be made to ensure that the vaccines we use are the safest and the best possible. Research dedicated to this goal must continue and increase, both in the Government and in the private sector. Modern technology must be applied to vaccine development and improvement. Positive experiences in other countries must be evaluated thoroughly. I look forward to the administration's testimony today regarding clinical studies of two new pertussis vaccines that appear to show great potential.

The Government and several medical organizations refer to a number of inevitable adverse consequences from vaccines. Clearly, the goal we must continue to pursue, as I mentioned before, is to minimize such consequences through improving vaccines. In the meantime, we need to ensure that physicians and other health care providers, and parents, are fully informed about all possible contraindications and side effects of vaccines. It is particularly important that parents understand clearly the special medical circumstances that mitigate against vaccine administration in certain children. It is essential that parents know about vaccine side effects, and especially about serious side effects or reactions that should be reported immediately to a health care provider and that signal caution for future vaccinations.

In that regard, I want to make a particular note of the efforts of Dissatisfied Parents Together [DPT], a private sector organization that has taken the initiative in producing and making available to the public an information pamphlet entitled "Pertussis and Pertussis Vaccine: Information for Parents." This is a major public service, and I commend DPT for it.

I am also very pleased to learn that both the American Academy of Pediatrics and the American Medical Association are increasing their efforts to remind physicians about contraindications and side effects, and to encourage physicians to discuss these things with parents. The Academy distributes several information items to pediatricians across the country, including a form that can be given to parents, listing side effects associated with the DTP vaccination, and indicating which reactions should be reported immediately to a doctor or a clinic. These are steps in the right direction, and I applaud the efforts and support their continuation and expansion.

Over the last year, there has been what some called a vaccine crisis. This has been brought about by a shortage of vaccines, due in part to difficulties that manufacturers have had in obtaining adequate liability insurance coverage. We understand that several manufacturers have been able to obtain insurance in the last few months, at increased premiums and with policies that are less than completely desirable. This, it seems, is only a temporary solution.

The question of assuring an adequate supply of safe and effective vaccines has to be dealt with. In part, this is going to mean dealing with the issue of unpredictable liability claims against manufacturers. I believe we will hear more than one solution to this particular problem proposed this morning. All approaches must be considered and judged on their own merits.

There are children who have been injured as a result of what are acknowledged to be inevitable adverse reactions to vaccines. Many believe that these children and their families are entitled to Federal compensation for costs associated with such injury or death. Various legal and administrative remedies have been suggested: in S. 827, in legislation introduced in the House of Representatives, and in a legislative proposal developed by the administration. These proposals all merit full consideration by this committee.

I want to thank all of our witnesses today, who came here from across the country to provide their particular points of view, advice, and guidance to the committee. In particular, I want to express my sincere gratitude and that of the committee to Mrs. Denise Judd of American Fork, Utah, for taking this long trip and appearing for the first time before a congressional committee to talk about her own family's tragic experience and about her personal efforts in Utah to work for parent information—efforts that will lead, in the long run, to an improved immunization program. Thank you, Mrs. Judd, for being with us today.

I also want to thank Senator Kennedy and Senator Hawkins for their interest in this subject, and their cooperation. In particular, I thank Senator Hawkins for the leadership that she has provided in this area.

With that, we will turn to you, Senator Kennedy.

Senator **KENNEDY**. Thank you very much, Mr. Chairman.

First of all, I want to express my appreciation to you for chairing these hearings and for giving focus to this extremely important public policy issue and question.

Vaccines are among the most valuable weapons in the medical arsenal. Programs of childhood vaccination have made an invaluable contribution to the control of such age-old scourges as smallpox, polio, measles, mumps, rubella, diphtheria, tetanus, and pertussis. Without these vaccines and the Federal commitment to a public health program of mass inoculation, hundreds of thousands—perhaps millions—of people who live healthy and productive lives today would be dead or disabled.

While the vaccines have brought the blessings of life and health to millions, vaccination has also meant tragedy for a few unfortunate members of our society. In some cases, vaccination has meant death or disease because of reactions that we do not fully understand and which are probably unavoidable until safer vaccines are developed.

In other cases, children have been unnecessarily injured by vaccines because providers and parents have been unaware that there are contraindications to the administration of even the safest vaccines.

The tort system is the traditional means of obtaining compensation for injuries in our society. It serves us well in many respects, but in the case of vaccines, it is no longer clear that the tort remedy truly serves the best interests of injured children and their families. Litigation is far too time consuming and expensive and exhausts resources that could be better used in compensating the injured child.

At the same time, the uncertainties about the extent of vaccine manufacturers' ultimate liability has substantially increased the cost of insurance, and may threaten the long-term availability of critical vaccines. We experienced a shortage of pertussis vaccine earlier this year because one manufacturer suddenly left the market, and there was some doubt whether the sole remaining manufacturer would remain in the market. Although that crisis is now over, we cannot assume that the problem is permanently solved.

The American people deserve to know that the supply of vaccines they need will remain available. Those few unfortunate children who are injured by vaccines deserve prompt and fair compensation for their suffering and access to necessary treatment.

We need to take action to assure that any vaccine-related injuries that are suffered are truly unavoidable, and we need to do our utmost to encourage development of the safest possible vaccines.

The bill we are considering today is an attempt to deal with all these important issues; the problem is a complex one. I look forward to the comments of our knowledgeable witnesses on the solutions suggested in this bill and on the legislative remedies offered by others, and I'm hopeful that this hearing and others that have been held on this issue will result in a solution that will guarantee fair compensation to victims, continued supply of important vaccines, and a reduction of vaccine injuries to the lowest possible level.

The **Chairman**. Thank you, Senator Kennedy.

We will turn to Senator Hawkins.

Senator **Hawkins**. Good morning. Today's hearing marks the fifth Senate hearing in 3 years on this subject, and represents the third bill that I have introduced on our National Childhood Immunization Program. It is a complex issue, but a very important one, and at each hearing we gather more and more information and support. We come just a little bit closer to solving this difficult and vital issue.

The first hearing I chaired was in April 1982. As chairman of the Subcommittee on Investigations and General Oversight, I prepared for hearings on the proposed budget reductions in the Federal Childhood Immunization Program.

Since that time, the Labor and Human Resources Committee has held four hearings on this one subject: May 7, 1982, on immunization and preventive medicine; July 23, 1982, on oversight of immunization costs; July 23, 1983, on the Pertussis Task Force Report; and May 7, 1984, on the National Childhood Vaccine Injury Compensation Act. I know the public thinks we're going to continue to have hearing after hearing after hearing and no action.

Fortunately, some people are starting to understand the problem and have a better understanding of the factors that are threatening the stability of the supply of vaccines, and thus threatening to prevent children from having these all too important vaccines.

I am alarmed at the dramatic increase in the price of DTP vaccine at the same time we're having a hearing—from 11 cents a dose in 1983 to $2.80 a dose just last year, to $4.29 a dose, which was announced this week by letter. The price increases are primarily attributable to the lawsuits that are pending against various vaccine manufacturers. We have learned that the tremendous increase in these suits can be traced to the number of adverse reactions, which we talked about in 1982, associated with the pertussis vaccination.

Efforts are being made to develop and test a safer vaccine for pertussis, but I believe we can't wait; I just hope that technology and scientific improvements will resolve this situation without some pressure from this body. Even assuming a problem-free, expedited consideration of the FDA applications, we are still years away from obtaining FDA approval of a new pertussis vaccine which, hopefully, will be equally effective but with fewer adverse reactions.

We are in the midst of a crisis in our Childhood Vaccination Program. The adverse reactions associated with the current vaccine are eroding the public's confidence in the Immunization Program itself. The withdrawal of two of the three pharmaceutical manufacturers of DTP from the market last year resulted in a shortage of the vaccine. That led to the unprecedented action of CDC advising physicians to delay giving the DTP booster shots in order to ensure a sufficient supply of the vaccine to immunize infants from these highly contagious diseases.

Thankfully, this shortage has been eased by Connaught's reentry into the market, and I thank them for that, but the liability concerns and considerations that prompted Wyeth and Connaught

Labs to cease distribution of the DTP vaccine are still confronting the distributors of the DTP vaccine.

It is obvious that a legislative solution is needed to stabilize the supply of childhood vaccines and restore public confidence in the Childhood Immunization Program. I know this can be achieved without sacrificing the legitimate needs and legal rights of children permanently injured by adverse reactions to a vaccine.

It is time to stop trying to assess the blame for the situation we find ourselves in; it's time to stop pretending that the problem will resolve itself. Instead, it's time to work together toward our common goals of improving the quality and the safety of childhood vaccines; it is time we assured a stable supply of safe vaccines to protect children from deadly and infectious diseases, and provide just and expedited compensation for those few children who are injured by an adverse reaction.

Last, I think that this hearing stands as a symbol of our commitment toward the common goal of a safe and equitable childhood immunization system. I am encouraged by the administration's appointment of a Cabinet-level task force on vaccines, and their acknowledgement, even after the initial supply shortage was eased, that a legislative solution is needed.

I am encouraged by the willingness of the vaccine manufacturers to speak openly and honestly about the problems and pressures facing them, as an industry; I'm encouraged by the parents that meet with us. I am encouraged by the pediatricians' willingness to review and to modify their original bill in order to address the concerns of other parties to this issue. I am very encouraged by the willingness of my Senate and House colleagues to address this now, before we are in another crisis situation, rather than legislate in a panic—which is our usual style.

With all these groups working toward a common goal, I think it's possible to enact legislation this session that will achieve all of our goals. With each hearing we hold, we gain additional support for a legislative solution; we are coming very close to achieving that delicate balance that we've been seeking so long. With the help of the witnesses that are brave enough to testify today, we can finally assure a stable supply of vaccines to immunize children against these dread diseases and provide increased protection and justice to the child victims of adverse reactions. I am looking forward to the witnesses' participation today.

Thank you, Mr. Chairman.

The **Chairman**. Thank you, Senator Hawkins.

We will turn to Senator Thurmond.

Senator **Thurmond**. Thank you. I will just take 1 minute.

Mr. Chairman, you and Senator Hawkins should be commended for the time and energy you have devoted to this issue of such vital national importance.

It is my belief that legislation is necessary to ensure that victims of childhood vaccines are equitably compensated, to provide for the continued availability of these vaccines, to increase research efforts to find a safe vaccine, and to protect the manufacturers and doctors who administer the vaccines from financial insolvency.

Unfortunately, obligations as chairman of the Judiciary Committee—we have a hearing at 10 o'clock this morning—and as a conferee on the Armed Services Committee prohibit me from remaining for the full hearing today. However, I look forward to reviewing the testimony of these witnesses and to the expedient passage of legislation which will adequately address the concerns expressed today.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Thurmond. Three of us this morning are obliged to attend a markup session in the Judiciary Committee, so we will have to leave, but Senator Hawkins will chair this hearing. I, personally, appreciate not only her interest, but her expertise in this area and the energy that she has expended in trying to resolve this issue; we are going to do everything we can to help her.

Our first witness this morning is Senator Dale Bumpers of Arkansas. Senator Bumpers and his wife have long been staunch supporters of the immunization program in their home State, and strong advocates of our National Childhood Immunization Program. Senator Bumpers is a cosponsor of S. 827.

Senator, we are grateful to have you here this morning. We welcome you to the Labor and Human Resources Committee, and we are very pleased to take your testimony at this time.

Senator KENNEDY. Mr. Chairman, could I join in welcoming Senator Bumpers to the committee. In the time, both that you have been chairman and when I was chairman, I don't think there has been a member of the Senate who has been as involved in this whole issue. I think all of us are enormously grateful for the efforts that Senator Bumpers has made over the past years on the floor of the U.S. Senate to continue the funding for an effective immunization program.

Senator Bumpers amendments only provide a few millions of additional dollars, and they have been too frequently rejected by the Senate, but they are essential for well-being and health of hundreds of thousands of children. So I, too, join in welcoming you to this committee, and I think all of us look forward to your testimony.

STATEMENT OF HON. DALE BUMPERS, A U.S. SENATOR FROM THE STATE OF ARKANSAS

Senator BUMPERS. Mr. Chairman, I thank you and Senator Kennedy both for your very kind remarks, and I want to thank the members of this committee for allowing me to appear here in support of S. 827 and I commend Senator Hawkins and other members who have put it together.

I am a staunch supporter of S. 827—it may not be a perfect bill, but I am sure as you get the markup on it, whatever flaws it may have will be remedied.

I have thought long and hard about children who are victims of vaccine-related injuries and the best way to try to make up for their tragic injuries. Although they are rare—a tiny fraction of the incidence of debilitating childhood diseases which would be inevitable if we didn't immunize our children—these injuries inflict an unspeakable burden on their victims and jeopardize the entire Childhood Immunization Program.

I am as reluctant as any of my colleagues to advocate a new Federal program, but the conclusion is inevitable that the long-term financial and human costs of endangering the immunization program or ignoring injured children far outweigh the risks of endorsing a new compensation system, particularly a voluntary one such as is set out in S. 827.

This bill provides the best means yet proposed for compensating injured children fairly and promptly, while guaranteeing that the immunization program continues uninterrupted.

As the chairman and Senator Kennedy have pointed out, Betty and I have been deeply involved in the Childhood Immunization Program since my early days as Governor.

Of course, what we all look forward to is a safe vaccine, but as Senator Hawkins has correctly pointed out, that is probably years away. Implementing an immunization program and seeing childhood diseases practically eradicated in the State were the most rewarding things that Betty and I did during my tenure as Governor.

Anyone who has seen his child suffer from tetanus, whooping cough, polio, or any other childhood disease knows the human benefits of eradicating these diseases.

Now, we are faced with a great paradox: Our National Immunization Program is so successful that many parents today really don't know how devastating these childhood diseases can be. They no longer take measles and mumps as the serious health threat they can be.

I am committed to seeing that young children and their mothers and fathers never have firsthand personal knowledge of the devastating consequences of childhood diseases. That commitment means insisting on adequate funding for the vaccine program itself and also fair compensation to children who, through no one's fault, develop the statistically inevitable vaccine-related injuries.

Now, Mr. Chairman, it has already been pointed out here that we have just come through a crisis of sorts on the availability of vaccines, and so I won't repeat what has already been said.

Unhappily, we all know, and we must be open about the fact that the use of the currently available vaccines will result in a polio-like illness in 1 of 5 million doses of polio vaccine, and a serious, permanent, neurological disorder will result from 1 in every 310,000 doses of DTP. These numbers won't improve until we have safer vaccines.

The suffering of these children who have vaccine-related injuries is well documented, and their right to compensation is obvious to a society which believes that those injured through no fault of their own should not have to bear their burdens alone.

One of the main reservations I have about this bill, of course, is its cost, and this concern cannot be dismissed, especially in these days of astronomical budget deficits. On the other hand, the cost of vaccines and, therefore, the cost of the immunization program itself will continue to increase alarmingly, perhaps endangering the program and our children's health if we don't address the problem of vaccine-related injuries.

The Centers for Disease Control estimates a 25-percent increase in measles, mumps, rubella vaccine costs for 1986, a 10-percent increase in polio vaccine costs, and a 10-percent increase in DTP vaccine costs. If these cost estimates were accurate, they would be the most reasonable increases in years, but already they seem to be conservative, and the costs of endangering the Immunization Program are astronomical.

A recent study showed that the cost-benefit ratio for this program is roughly 14 to 1. Fourteen dollars saved for every dollar spent, and other vaccines have similarly impressive benefit-cost ratios.

Again, Madame Chairman, if I may digress from my prepared statement, and tell a slightly self-serving story. When I first came to the Senate, Betty wanted to continue doing at the national level what she had done at the State level and, quite frankly, got absolutely no cooperation.

But when President Carter came to town, Betty immediately hiked over to the White House and sold President Carter on a national immunization program.

He immediately called Secretary Califano and told him to cooperate with her—and because of that massive effort in 1977, we raised immunization levels to almost 97 to 98 percent in this country.

I remember the day in 1977 that they announced that they had achieved 97 to 98 percent immunization levels in the country, Secretary Califano announced that it was the Department's determination that that program would save $18 billion a year, not just in avoided health-care costs, but also in man—and woman—days spent at home with children who were ill with these diseases.

Well, if those numbers are turned around and the costs of curtailing our immunization program are obvious—$14 in future health care cost for each $1 saved—then of, course, that is the most perverse kinds of saving anybody could recommend.

S. 827 has several important features. It provides for an optional compensation system so injured children and their families can still go through the traditional judicial system if they choose litigation over the alternative compensation system. It requires a prompt settlement of claims. It mandates the pursuit of new and improved vaccines, and it requires the reporting of vaccine reactions.

Much work has been done on this bill by parents, the American Academy of Pediatrics, and by Senators and their staffs. This bill has been vastly improved over the proposals debated in the last Congress, and I hope our colleagues can be persuaded of the pressing need to address this issue in this session.

My interest in a vaccine injury compensation bill springs from my desire to see the Immunization Program continue and go forward, not backward, and from my strong commitment to securing fair treatment for those children who are tragically injured as a result of complying with our immunization laws. The two issues are intertwined. and only a fair compensation system can provide for injured children and guarantee that the Immunization Program succeeds.

Madame Chairman, I thank you very much for allowing me to be here. I will be happy to answer any questions if the committee has any.

Senator **Hawkins** [presiding]. I thank you for being here. You and your wife are to be commended for being leaders in this great effort to have safer childhood vaccines.

Senator **Bumpers**. Thank you.

[The prepared statement of Senator Bumpers follows:]

Statement of Senator Dale Bumpers

before the

Senate Committee on Labor and Human Resources

on

S. 827, the National Childhood Vaccine Injury Compensation Act of 1985

July 18, 1985

I want to thank members of the Labor and Human Resources Committee for allowing me to appear here today to speak in support of S. 827, the National Childhood Vaccine Injury Compensation Act of 1985. The Committee is to be commended for initiating this serious discussion of a responsible, timely bill which offers the hope of a fair and prompt system of compensation for a small portion of our children to whom fate has dealt a cruel hand.

I have thought long and hard about the children who are victims of vaccine-related injuries and the best way to try to make up for their tragic injuries. Although these injuries are rare -- a tiny fraction of the incidence of debilitating childhood diseases which would be inevitable if we did not immunize our children -- they inflict an unspeakable burden on their victims and jeopardize the entire childhood immunization program. I am as reluctant as any of my colleagues to advocate a new federal program. But the conclusion is inevitable that the long-term financial and human costs of endangering the immunization program or ignoring injured children far outweigh the risks of endorsing a new compensation system, particularly a voluntary one as is proposed in S. 827. This bill provides the best means yet proposed for compensating injured children fairly and promptly, while guaranteeing that the immunization program continues uninterrupted.

Betty and I have been involved in the childhood immunization program since my days as governor of Arkansas. Implementing an immunization program and seeing childhood diseases practically eradicated in the state were among the most rewarding things I did as governor. Anyone who has seen a child suffer from tetanus, whooping cough, polio or many other childhood diseases knows the human benefits of eradicating these diseases.

We are now faced with a great paradox: our national immunization program is so successful that many parents today really don't know how devastating childhood diseases can be. They no longer take measles and mumps as the serious health threat they can be. I am committed to seeing that young children and their mothers and fathers never have firsthand, personal knowledge of the devastating consequences of childhood diseases. That commitment means insisting on adequate funding for the vaccine program itself and also fair compensation for children who, through no one's fault, develop the statistically inevitable vaccine-related injuries.

This past year, the immunization program has faced serious supply problems for DTP vaccine, and many regions of the country experienced spot shortages of the DTP vaccine. These problems occurred because one manufacturer dropped out of the market, another halted distribution of DTP, and the remaining manufacturer recalled a batch of DTP. Two of those events were directly related to liability problems facing manufacturers. Emergency measures to delay DTP booster shots and the return of two manufacturers to the market alleviated the supply problems, and the alarms sounded by the shortages directed our attention to the vulnerability of children suffering from vaccine-related injuries and of the entire program.

Unhappily, we know that the use of the currently available vaccines will result in a polio-like illness in one of 5,000,000 doses of polio vaccine, and a serious, permanent neurological disorder will result from one in every 310,000 doses of DTP. These numbers will not improve until we have safer vaccines. The suffering of these children who have vaccine-related injuries is well documented, and their right to some sort of compensation is obvious to a society which believes that those injured through no fault of their own should not have to bear their burdens alone.

One of the main reservations that will be raised about S.827 is its cost. This concern cannot be dismissed, especially in these days of astronomical budget deficits. On the other hand, the costs of vaccines and, therefore cost of the the immunization program itself, will continue to increase alarmingly --perhaps endangering the program and our children's health --if we don't address the problem of vaccine-related injuries. The Centers for Disease Control estimates a 25 percent increase in measles-mumps-rubella vaccine costs for 1986, a 10 percent increase in polio vaccine costs, and a 10 percent increase in DTP vaccine costs. If these cost estimates were accurate, they would be the most reasonable increases in years, but already they appear to be conservative. And the costs of endangering the immunization program are astronomical. A recent study found that the benefit-cost ratio of the measles-mumps-rubella immunization program is 14 to 1, and other vaccines have similarly impressive benefit-cost ratios. If those numbers are turned around, the costs of curtailing our immunization program are obvious -- $14 in future health costs for each $1 "saved" by reducing vaccinations.

S. 827 has several important features: it provides for an optional compensation system, so injured children and their families can still go through the traditional, judicial system if they choose litigation over the alternative compensation system; it requires a prompt settlement of claims; it mandates the pursuit of new and improved vaccines; and it requires the reporting of vaccine reactions. Much work has been done on this bill by parents, the American Academy of Pediatrics, and by Senators and their staffs. This bill has been vastly improved over the proposals debated in the last Congress, and I hope our colleagues can be persuaded of the pressing need to address this issue.

My interest in a vaccine injury compensation bill springs from my desire to see the immunization program go forward, not backward, and from my strong commitment to securing fair treatment for those children who are tragically injured as a result of complying with our immunization laws. The two issues are intertwined, and only a fair compensation system can provide for injured children and guarantee that the immunization program goes on.

Senator **Hawkins**. Thank you for your support, and I believe we are gathering other support. You may be excused at this time.

Senator Stafford has joined us and has a statement.

Senator **Stafford**. Thank you, Madame Chairman.

This committee's action will be important, not only in and of itself, but because of the precedent it may establish for other areas. What we have before us is a legislative proposal to compensate the victims of DTP vaccines.

Later this morning, the committee will hear the tragic stories of fathers and mothers whose children died because of this vaccine.

Five years ago this same committee heard from another panel of fathers and mothers They were seated at the same table in this very same room, and the story they had to tell was remarkably similar.

They, too, had lost sons and daughters, but their children had been the victims of chemicals which had poisoned their drinking water.

Last Friday, this Senator chaired a hearing of the Committee on Environment and Public Works on the progress of schools in this country in removing asbestos. One young woman who might have testified, but could not, was from New Jersey. Her testimony would have been relevant because she is incurably ill, almost certainly because of the asbestos to which she has been exposed in her classroom.

Four days after that hearing my staff received a telephone call from a father who had watched our hearing on cable television. His son, he said, was also incurably ill because of asbestos. Tragically, the father himself was in the asbestos business and had helped his son to get his start in a similar enterprise.

My point is that the plight of these parents is by no means unique. Similarly, the complaints which we are likely to hear from the manufacturers and dispensers of DTP vaccine are not unique.

This Senator is satisfied that the innocent victims of our chemical and technological revolution should be compensated. Indeed, the United States is the only industrialized nation in the world which has failed, through some means or other, to confront and deal with the plight of such victims.

But our overriding concern should not be to compensate victims; rather, we should try for a program which ultimately assures that there are no victims to be compensated. This Senator's goal is to return to this room a few years from now to find that there are no parents to sit at the table here, or in any other committee room, with tragic tales of children whom they have buried.

Our obligation is not to the drug companies nor the doctors. Indeed, our highest obligation is not even to the parents who may have suffered grievously; our highest obligation is to the children. Whatever we do should operate to the maximum extent to induce the highest standards of care. The safest possible vaccine should be dispensed in the safest possible manner. Any provision which diminishes such a standard of care has no place in legislation such as this.

It is for this reason that some would question suggestions that injured parties should be barred from the courtroom, or that the liability of those who make and dispense DTP vaccines should be limited.

Whatever action this Committee ultimately takes, it should not remove or diminish the incentives for care which already exist, nor should it seek to provide compensation which is less than complete. It would be better to do nothing at all than to enact legislation which resulted in less safe vaccines, administered under less safe conditions.

Thank you, Madame Chairman. I have a series of questions for Dr. Mason, Mr. Willmore, for parents and for the industrial panel that I ask be submitted to them in writing, if that's agreeable to the chairman.

Senator **Hawkins**. So ordered.

Do you have any questions for Senator Bumpers?

Senator **Stafford**. No. I simply want to compliment the Senator, as usual, on his appearance here and the kind of presentation, Madame Chairman, which he always makes.

[The prepared statement of Senator Stafford follows:]

Statement of Robert T. Stafford

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Senator **Bumpers**. I thank the Senator from Vermont.

Madame Chairman, if I may just add one addendum to my other statement, it is this: there is nothing more heart-rending than what this committee is about to see and hear today. We all recognize that, and the television news services concentrate on that very dramatically, and it's frightening to parents of young children who are about to be required to take these shots. As the father of three, I certainly empathize and understand that; and that's one of the reasons that I feel so strongly about this bill.

On the other hand, the statistics are absolutely overwhelmingly, and the American Academy of Pediatrics consistently makes this point, which, unhappily, the newsstories very seldom do, and that is that the heart-rending stories would probably be three or four times as great if we dropped this program or allowed parents to stop participating in it. The British tried it and got up to 29 deaths per year from creating a situation which made pertussis a possibility there.

As I say, I'm sure the American Academy of Pediatrics is going to be here today, and they will reemphasize that, but I think that point must not be lost.

Madam Chairman, thank you again for allowing me to be here.

Senator **Hawkins**. Thank you. And I think Senator Stafford is on the right trail, and we are on the right track when we're developing a safe vaccine. With a safe vaccine, we have the solution to a lot of our problems.

Before we proceed with the first panel we will receive for the record statements by Senators Metzenbaum, Quayle, and Grassley.

[The prepared statements of Senators Metzenbaum, Quayle, and Grassley, follow:]

Prepared Statement of Senator Metzenbaum

Mr. Chairman, I am pleased that this committee is holding another hearing on compensation issues surrounding the DPT vaccine.

Legislation has been introduced in the Senate this session which merits our very close attention. The record compiled at this hearing should assist those of us who have a number of questions about how the interests of parents and their children can best be served.

I want to express my thanks to the parent groups who have put a tremendous amount of effort into reaching a compromise piece of legislation on this issue.

I have no doubt that if it were not for their determination to keep this issue on the front burner, we would not be here today examining the latest proposals on compensation injuries caused by the DPT vaccine. They have been a constructive force in this debate.

And I feel strongly that the questions which they continue to raise must be answered, Why don't we have a safer vaccine on the market today? Why hasn't the Department of Health and Human Services taken an active role in encouraging the development of new vaccines and acted as a vigilant watchdog against the marketing of "bad batches" of DPT vaccine? Why haven't parents received full and adequate advice about the use of the DPT vaccine?

Finally, and most importantly, why have the parents of children who have been damaged by the vaccine gotten the feeling that all the government wants to do is sweep the problem underneath some bureaucratic carpet and hope it will go away?

We owe these parents answers to these questions. We also owe them a fair system of compensation. I compliment all those who have worked so hard on this issue and I look forward to doing what I can to move this issue along.

Statement of U.S. Senator Dan Quayle (R-IN) for
Senate Labor and Human Resources Committee Hearing on
"Childhood Immunization: Problems and Options"

July 18, 1985

Mr. Chairman, before making some comments with regard to my concerns related to vaccine injuries and compensation, I would like to congratulate you for holding this hearing on such a potentially important public healh problem and particularly Senator Hawkins for the tremendous amount of work she has put into this subject. She has worked long and hard to educate the members of this Committee about the problems of vaccine compensation and to try to find an acceptable solution to the problem.

This hearing was called to discuss what approaches the Congress should take to try to remedy a very real and immediate problem --- the need to preserve our country's very fine and effective immunization programs by ensuring widespread confidence in the safety and efficacy of vaccines in order to continue widespread participation in the program. To accomplish this we must be able to provide timely, equitable compensation to injured children for vaccine caused and related injuries and to provide manufacturers of the vaccine with a sufficient economic incentives to continue producing a sufficient supply of vaccines.

Clearly the heart of the problem lies not with the manufacturers, the physicians or the parents but with our current tort system for compensating such injuries. I think this is the one area where all our witnesses agree --- in such cases the tort system benefits no one. Certainly, the injured child and his or her family are not benefited by the fact that it takes years for our legal system to reach a settlement and to award claims. Nor is it fair to the vaccine manufacturers whose liability insurance is threatened through no fault of their own because of the financial vagaries involved in such settlements which make it impossible for them to predict their potential liability with any certainty.

While I think there is agreement on the cause of the problems we are currently facing, I do not think there is currently a consensus among the people in this room about what legislative solution this Committee should pursue to remedy them. A number of alternatives exist, albeit all of them pose problems:

o Elminiate access to the tort system for this type of injury or at least limit awards. Several variations of this approach have been suggested. Is this appropriate interference by the Federal government in an area traditionally reserved to the States? Would such an approach deprive victims of property without due process? Would it affect the incentive of the manufacturer to improve their products?

o Provide for a "no fault" compensation program outside the tort system. If such compensation is less than what an individual felt would have been awarded under the tort system, would this deprive victims of property without due process? How would such awards be financed? Is a surcharge on the manufacturer reasonable and workable? Would it add significantly to consumer costs of the vaccine?

o Provide for a publicly financed or mandated program for immunization programs mandated by State law. Would this really solve any of the current problems?

o Encourage health insurance plans to include compensation for vaccine related injuries.

These are just some of the alternatives this Committee can examine. The one thing that I hope will come out of this hearing is some consensus among the participants about what approach this Committee should realistically begin to develop.

I believe that the problems involved in vaccine compensation require a timely and equitable solution but I must emphasize that all parties must be willing to compromise if this Committee is to be able to move legislation in the near future. I look forward to working with all of you to reach such a compromise.

STATEMENT OF SENATOR CHARLES E. GRASSLEY ON S. 827, THE NATIONAL VACCINE INJURY COMPENSATION ACT OF 1985, BEFORE THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES, THURSDAY, JULY 18, 1985

I want to commend Senators Hawkins and Hatch and their staff for their efforts to develop a legislative solution to the problem of vaccine-related injuries which threaten the viability of our immunization system. As I pointed out a year ago at the last hearing this committee held on this topic, over the course of what have now been four hearings, today's being the fifth, we have identified a number of goals we should strive to achieve with respect to this problem. I will just reiterate them briefly here.

First, we should strive to maintain the viability of our childhood immunization program. Immunization of children has been spectacularly successful. A number of life-threatening children's diseases have either been eliminated or all but eliminated as a result of our immunization programs. Furthermore, the benefits of immunization far outweigh the risks. It is important to make this point because many of our younger parents have no direct memory of the devastating effects childhood epidemics can have. It seems to me that we must insist on this point because, as the experience of other countries indicates very clearly, if public confidence in our immunization system erodes and the level of immunization declines, the consequences could be catastrophic.

Second, we need to do all that is possible to eliminate all adverse effects of vaccines, both through development of safer vaccines, and through better parent and physician awareness of potential problems.

Third, we need to do more to improve our knowledge of the extent, patterns, and causes of adverse reactions to vaccines.

Fourth, I think we have achieved a consensus on the question of whether compensation for children who are clearly injured by vaccines is in order. Clearly, it is. In most of our states, vaccination is required before a child will be allowed to enter public school. Federal, state and local government officials urge all parents to immunize their children. For all practical purposes, immunization programs have become obligatory. Should a child sustain injury as a consequence of such an immunization program, it is clearly unjust that that child or its parents should sustain the entire burden of the consequences which may follow.

Fifth, and finally, there seems to be consensus also to the effect that our present system of compensating people who are injured by vaccines is not equitable and reasonable - that it compensates in a fair and timely way those children who have been injured by vaccines.

Our present system may have also contributed, through large liability awards, to raising vaccine prices, and to causing American companies to leave the field of vaccine production. Just how important liability awards have been in this is not clear. In any case, it is argued that some sort of new compensation system is a good idea not only because such a program would do simple justice to injured children, but also because, by introducing predictability into the liability arena, it would help insure that American manufacturers continue to produce affordable vaccines.

Beyond these points, however, when we get to the details of legislation, and particularly on the compensation system we will adopt, we have not achieved consensus. There is great concern in many quarters, for instance: that a no-fault system for vaccine injury compensation will set an unfortunate precedent for product liability more generally. I hope our hearing today can help move us forward to greater consensus on the major issues in dispute.

In any case, this will be our fifth hearing, and it does seem to me that we are coming to the point at which the Congress must act to insure that our immunization system remains viable.

Senator HAWKINS. Our next panel will be a panel of parents whose children have been injured by an adverse reaction to childhood vaccine, and who have a strong interest in the various legislative proposals under consideration by Congress: Mrs. Denise Judd of American Fork, UT, whom Senator Hatch has already introduced; Mr. Jeff Schwartz, president of Dissatisfied Parents Together; and Mrs. Marge Grant, President of Determined Parents to Stop Hurting Our Tots.

I am anxious to hear all of your testimony.

Senator Weicker also sends his regrets, and has questions for other panelists.

All Senators have 24 hours to have their statements in the record and to submit questions for the witnesses.

Mrs. Judd, we will start with you today. Welcome.

STATEMENTS OF DENISE JUDD, AMERICAN FORK, UT; JEFFREY H. SCHWARTZ, PRESIDENT, DISSATISFIED PARENTS TOGETHER [DPT]; AND MARGE GRANT, PRESIDENT, DETERMINED PARENTS TO STOP HURTING OUR TOTS [DPT SHOT]

Mrs. JUDD. Thank you. My name is Denise Judd. I live in American Fork, UT, with my husband and our five daughters. I am organizing the Utah group of Dissatisfied Parents Together, the national parent organization that has coauthored S. 827, and is working to educate the public about the pertussis vaccine.

I would like to thank the members of this committee for inviting me to speak about what has happened to my only son, Bronson, who died after he received his first DTP shot.

First, I would like say to Senator Hatch that I am proud to be a citizen of Utah because you represent me and many other parents and children by supporting S. 827. Your support of this bill and this hearing shows that you care about us. It is hard sometimes to believe that Senators and Congressmen really listen to the people. We know that you are listening.

I heard that you promised a group of Utah pediatricians that when it comes to vaccine injury compensation legislation, you will not legislate in the dark. That is a very important promise. I know you were referring to the book, "DTP: A Shot in the Dark," which tells the stories of so many DTP-damaged children and their parents. We hope that you and other Members of the Congress will read "DTP: A Shot in the Dark," and understand why we so desperately need a congressional investigation. We need to find out what is wrong with a system that has allowed such a reactive vaccine to be given to our children for the past 40 years.

We pray that the Congress will first investigate and find out where the changes need to be made so that fewer babies are hurt by vaccines. Then we hope you will pass S. 827 to help parents like us, who are almost in bankruptcy because we could not afford to bury our child or pay his medical expenses after the DTP shot killed him.

Now, I will tell you what happened to my baby after he got his first DTP shot. Bronson and his twin sister Brenda were just 2 months old when I took them to the doctor for a routine checkup one afternoon in July 1979. The doctor gave my babies physicals and said they were in very good health. Then he gave them each a DTP shot.

The next day Bronson slept a lot. He didn't cry to be fed, as he usually did. He just slept. At 4 in the morning I tried to feed him, as I usually did, but he wouldn't open his mouth to eat. He looked fine and didn't feel hot or anything, but I thought it was kind of strange that he wasn't hungry. At 9 a.m. I tried to feed him again, and I noticed he was very pale. Then his eyes started to roll back and forth in his head. I realized that he couldn't open his mouth to eat.

So, I opened his mouth for him because I knew he had to be hungry. He guzzled 2 ounces of formula down in 1 minute, which I thought to myself, "This isn't normal," because he was drinking it too fast.

He moaned when I picked him up as if I had hurt him. When I changed his pants, I found strange diarrhea and clumps of mucus. I knew something was wrong.

My sister rushed us to the hospital at American Fork. The doctors thought he might have aspirated something in the night so they stuck tubes down his throat to pump his stomach, and he started gagging. Then Bronson went into cardiac arrest. They couldn't get him breathing again for 3 minutes. When he did start breathing, he had a blue mark on the side of his head, so we knew our baby had already received brain damage.

Then they put him in an ambulance and sent us to a hospital in Provo. He had cardiac arrest several times in the ambulance. By this time, he was paralyzed on the right side; and later that night we were taken by ambulance from the hospital in Provo to a hospital in Salt Lake City.

The doctors couldn't get needles in his arms; they said his veins had collapsed. They couldn't get needles in his legs; they were also collapsed, so they had to put needles in his head. They even tried to exchange fluids through his naval.

Finally, they came in and said to my husband and I: "He's not breathing on his own at all." Then our son died. I can't tell you how terrible it was to watch my baby die in such pain, to see the doctors have to put so many needles in his little body. I couldn't believe that my son was paralyzed, that he was dying. He had been so healthy until he got his shot.

We were lucky Bronson's twin sister survived. When we got home, we discovered that Brenda was very sick, too; but it wasn't as bad for her, and she made it. Today, she is 6 years old, but still wakes up screaming strangely in the night. Her teacher says she is hyperactive and can't concentrate well.

From the moment Bronson died, my family believed it was due to the DTP shot. Although the doctors would not admit the DTP shot killed him, a Utah official in the CDC told me on the telephone that Bronson died of a reaction to his DTP shot, but he told me that he would not say that to anyone else. He said: "Denise, between you and I, your son died from the DTP shot." He also said that Bronson's death was the only one in Utah in the last 3 years that was due to the DTP vaccine.

In order to buy a casket for our son Bronson, to pay for his funeral, and to pay the huge medical bills from the three hospitals who saw him during the hours he was dying, we had to take out a second mortgage on our home. We got further and further into debt. We had to borrow money from our relatives, and the second mortgage was ruining us, and soon we were near bankruptcy.

We tried to find a lawyer to file a lawsuit. The lawyers said we had an excellent case, but they wouldn't take it because Bronson had died. They said they would have taken it if Bronson had lived and had brain damage. They explained to us that it costs more money to bring a lawsuit in a death case than can be won to pay the legal fees.

So, we had no way to pay the medical and funeral bills that resulted from Bronson's death. Last year, we were just 4 days from foreclosure, 4 days from our home being taken away from us, when a relative saved us with a loan again.

We have finally found a lawyer to help us bring a lawsuit, but we feel strongly that our suffering would have been much less if the Federal compensation bill, S. 827, coauthored by Dissatisfied Parents Together, would have been there for us after our son Bronson died.

It only seems right that if our country is going to recommend that children be vaccinated, then there should be a way for parents to get help when a vaccine hurts or kills a child. We shouldn't be left alone to suffer the consequences of following that recommendation.

It hurts so bad when you lose a child. Every time I see a 6-year-old boy, I think of Bronson, of what he would have been like today. You never forget it and you never get over it. And when your whole life is ruined financially, like ours has been, it is almost too much to cope with.

All we want is justice. We want you to do something to help us make our baby's death, and the deaths and vaccine injuries of so many other children, mean something. Don't pass a bad compensation bill that takes away a parent's freedom to go to court or that unjustly limits compensation in the court system. That is not justice. And don't pass a bill that doesn't have safety provisions. What good is a compensation bill that doesn't help prevent future vaccine injuries?

I can never bring back our son Bronson. The doctors tell me I can't have any more children, so I will never give birth to another son. But I can work to make this world safer for other babies and their trusting parents, and so can you.

Please call for an investigation and then pass S. 827 which is the only Federal compensation bill that truly cares about children and their parents.

Thank you.

Senator HAWKINS. Thank you, Mrs. Judd, for your eloquent testimony of the sacrifices made by the families, in addition to the loss of the life of the child.

Was that the first DTP shot that Bronson had had?

Mrs. JUDD. Yes, it was.

Senator HAWKINS. Did Bronson's twin sister, Brenda, have the second shot?

Mrs. JUDD. No, she didn't. She had the DT, and in a half dose.

Senator HAWKINS. They left the pertussis out the second time?

Mrs. **JUDD**. I was a little bit nervous.

Senator **HAWKINS**. At what age was Brenda given the second shot?

Mrs. **JUDD**. I think it was a year later. I was pretty scared.

Senator **HAWKINS**. She had no reaction when they took the pertussis out? With the DT?

Mrs. **JUDD**. No, no, she didn't.

Senator **HAWKINS**. Your other children had no reaction to these shots when you had them at the proper age?

Mrs. **JUDD**. All of our other—previously or——

Senator **HAWKINS**. Yes.

Mrs. **JUDD**. OK. Previously, no. Our first two did not have any reaction.

Senator **HAWKINS**. So you had no reason to be nervous?

Mrs. **JUDD**. I was not alarmed by it; I had not heard anything.

Senator **HAWKINS**. Were there any notices in the physician's office, as you sat there, telling you to look for signs of adverse reaction?

Mrs. **JUDD**. I didn't see anything. I had no idea what was going on when I was at home with him.

Senator **HAWKINS**. And nothing was given to you in the office by the physician, telling you to watch out for the following signs——

Mrs. **JUDD**. No, there wasn't.

Senator **HAWKINS** [continuing]. And to report them to the physician if any of these things happened to the child?

Mrs. **JUDD**. All my doctor told me there might be a slight fever, slight redness, a little irritation, and they said just give them a Tylenol. And they said if there's anything out of the ordinary—but I had no idea what "out of the ordinary" was—to call them and let them know.

Senator **HAWKINS**. And you were billed for all of the charges from each of the hospitals?

Mrs. **JUDD**. Yes, we were. We have not had any insurance at all.

Senator **HAWKINS**. You had no——

Mrs. **JUDD**. No life insurance. My husband is in construction, and so it's really been hard for him to work for someone that provides insurance.

Senator **HAWKINS**. Among your friends, is it usual to have life insurance on a 2-month old baby?

Mrs. **JUDD**. Unusual?

Senator **HAWKINS**. Yes. Do you find it usual or unusual?

Mrs. **JUDD**. I don't know.

Senator **HAWKINS**. I'll have someone bring you this notice, DTP Information Sheet, which is now published by the American Academy of Pediatrics, and it states, "Your child has just received the first, second, third, fourth, fifth shot of the DTP vaccine," and it underlines—circles the one, and under that it says, "The following conditions are usual reactions you may expect your child to have:" The first is fever, as you were told, irritability for up to 2 days, some soreness and swelling at the injection site.

Then it states, "The following reactions are less common. If your child displays any of them, please call my office," and it list the following: "High-pitched, peristent crying for more than 3 hours, excessive sleepiness or difficulty in rousing the infant, limpness or paleness, temperature of 103 degrees or higher, convulsion," and then it states, "Most vaccine reactions are not significant and will disappear a few days after your child has been vaccinated. Occasionally, however, a problem is identified after a DTP shot is given. Please call me to report any reaction you suspect is serious so your child can be examined and treated, if necessary." And then the doctor's name is listed, his address and the phone number where you can reach him.

Would this have been of assistance to you, had you had this?

Mrs. JUDD. Yes, it would have.

Senator HAWKINS. And you have never seen one of these with your other children either?

Mrs. JUDD. No, I haven't. I didn't know that they had any kind of a sheet.

Senator HAWKINS. These are signs that are now being displayed by the American Academy of Pediatrics in pediatricians' offices, so you can look at this while you are in his office waiting for the vaccine.

Mrs. JUDD. Great.

Senator HAWKINS. I thought I would like to show that to you and to other parents everywhere to look for these. If they are not in your pediatrician's office, your doctor's office, they should be.

The American Academy is working very closely with this committee to make sure that more information is given to the parents, and adequate information given to the parents.

Senator Nickles has joined us, and Senator Kerry.

Senator Nickles, do you have a statement?

Senator NICKLES. Madame Chairman, I don't have a statement, but I compliment you on this hearing, and I look forward to hearing the statements. Certainly, the first witness had a very moving statement and a very difficult tragedy in her life, and I appreciate the leadership that you are showing in trying to, hopefully, help resolve some of the difficulties that occur. I'm not sure exactly what the best approach is, but I do appreciate hearing our panelists and, again, my sympathies to you, Mrs. Judd, for the difficulties that you have been through. I hope that your story will help lead us in the right direction.

Thank you.

Senator HAWKINS. Senator Kerry?

Senator KERRY. Thank you very much, Madame Chairman.

I have a statement which I would simply like to insert in the record, and if I may have the unanimous consent to do so, I would appreciate it.

Senator HAWKINS. So ordered.

Senator KERRY. Mrs. Judd, I join with my colleagues here in thanking you very much for what I know is extremely difficult testimony, and I really appreciate both your traveling this distance, as well as putting yourself through this. We are very appreciative.

I would just ask you one question, and perhaps it may develop into a couple. Would the materials which Senator Hawkins has shown you and the notion of a posting in the physician's office, or such kinds of notices, been adequate means for conveying information to you? Do you have a sense that you would have taken notice of such information, or is there a better way that you have sensed, through this experience, that parents might be better advised as to the risks of vaccines?

Mrs. JUDD. Well, I feel that if I was able to read something other than what they told me the normal reaction would be, I would have been able to take him in that very next day instead of letting him sleep.

Senator KERRY. As we consider how we approach this vaccine issue—with respect to both compensation as well as the whole issue, in general—what do you think would be a good or better way to try to let parents be fully aware, of the various considerations associated with vaccines, or make sure that they are?

Mrs. JUDD. To provide information beforehand.

Senator KERRY. What kind? What type of information?

Mrs. JUDD. The immunization sheet saying what the good and the bad is, so we would know what to watch for.

Senator KERRY. And you hadn't known about it?

Mrs. JUDD. No, I didn't.

Senator KERRY. And you had not heard from other parents? There was no——

Mrs. JUDD. I had no idea the shot could do that.

Senator KERRY. Thank you. Thank you, Mrs. Judd.

[The prepared statement of Senator Kerry follows:]

STATEMENT OF
SENATOR JOHN KERRY

HEARING ON CHILDHOOD IMMUNIZATION:
PROBLEMS AND OPTIONS

COMMITTEE ON LABOR AND
HUMAN RESOURCES

JULY 18, 1985

I would like to commend Senator Hawkins and other members of this Committee and the Congress -- and especially those caring citizens -- who have worked so diligently in addressing the problems associated with the issue of childhood immunization.

Although these problems are complex, our goals in seeking their resolution must remain simple and clear. Ultimately, any solutions we contemplate should serve the public health and should preserve the traditional American values of fairness and equity. We already know that achieving a balance in these goals may be difficult, especially in light of the fact that we have many objectives we also need to satisfy along the way: we need adequate monitoring, information and education programs; we need a public health system which deserves public confidence; and we need more scientific understanding about vaccines and how they work.

Unfortunately, in the past with some other issues, we have seen that as we attempt to correct one problem, we sometimes inadvertently create another. In considering vaccine issues, I believe we must carefully take into account the possible ramifications of all proposals within the context of each other, and as I review today's testimony, I will be taking that approach.

Our children are those most precious to us. Legal and legislative controversies must not cloud or confuse our commitment to their health and safety. I look forward to working with all those who share that commitment as we seek to assure a safe and adequate vaccine supply and a fair compensation system for those who have suffered injuries from vaccines.

Senator HAWKINS. My concerns, Mrs. Judd, are not only the loss of your child, but the expenses that you incurred due to this terrible tragedy. I don't know that this piece of legislation will be the perfect solution to these immediate costs that are incurred in a family such as yours when the tragedy strikes, in the absence of insurance on a 2-month-old, 3-month-old infant, whatever age the child is vaccinated.

Could you give us an approximation of how much the expenses were, say, the first 6 months?

Mrs. JUDD. I couldn't——

Senator HAWKINS. You don't know?

Mrs. JUDD. I have no idea.

Senator HAWKINS. But it would be three hospitals, I believe you said, at least?

Mrs. JUDD. Yes. And several doctors, ambulances.

Senator HAWKINS. The funeral.

Mrs. JUDD. Yes, and a cemetery lot. We had to go all out; we had nothing.

Senator HAWKINS. And your husband—did you say that he had trouble finding work?

Mrs. JUDD. He is in construction, so it's an up and down line of work.

Senator HAWKINS. Construction. Is he self-employed?

Mrs. JUDD. He was part of last year, and other times he worked for other contractors.

Senator HAWKINS. OK. I appreciate your helping us here today. All this testimony really does help us tailor a bill that will meet the needs of those very few people who have this reaction, an adverse reaction which, as you stated, is in the common good of innoculating so many other children that don't have these diseases due to the innoculation. There are a few that have this reaction, and I feel they should be compensated quickly; and also, you should have the opportunity to pursue recovery in the courts if you so wish.

Jeff, welcome back—we've become good friends. I know that you and your wife have good news for us today, that you are expecting a child, and my congratulations to you. I hope that everything goes well. I know you have had an awful difficult time having this baby. And because of the emotional strain of the legal proceedings that you are involved with, you have decided to delay your lawsuit over Julie's death, but can you briefly describe—bring us up to date on the condition of your wife and your family, and how draining is it, and what are the procedures for pursuing a lawsuit for parents of a damaged child?

Mr. SCHWARTZ. Senator, I have to apologize: I have some kind of persistent ear infection in both ears, which is making it very difficult for me to hear, so I hope I will be responsive.

We have found the whole process of filing a lawsuit and going forward with it a very difficult and unpleasant experience, but there was no alternative—there is no alternative and no way to get anyone to acknowledge responsibility for Julie's death, and this litigation was the only way to get at the truth.

We started it before we were aware that Donna was pregnant. Eventually, we felt that the stress that would be induced by the litigation was too great and so we have moved to try and put aside the case for the time being until, hopefully, the pregnancy can be completed successfully.

Senator HAWKINS. You have been very successful in the leadership of the group of parents who have discovered this is a problem more common than previously thought, I guess, before the hearings and before the public's attention was brought to this.

Do you have any numbers you would like to share with the Committee?

Mr. SCHWARTZ. I think—I'm very wary about numbers, Senator Hawkins, and one of the things I urge the committee to do is, be wary of these numbers. The numbers are very facile and easy—our numbers or anyone else's ought to be looked at very carefully.

The statement that only 50 children a year are permanently damaged by DTP vaccine just can't be substantiated, but we can't tell you how many there are either because we don't have an adequate system for tracking—for reporting reactions and tracking long-term effects. And the studies are just grossly inadequate in this area. So we can't tell you how many, but we can tell you that there are too many.

Senator HAWKINS. One is too many.

Mr. SCHWARTZ. Right.

Senator HAWKINS. I know you have a statement, do you not?

Mr. SCHWARTZ. Yes, I do, Senator Hawkins.

Senator HAWKINS. If you could give us a 5-minute summary, due to time constraints, and I will make sure that the entire testimony is submitted in the record for all of the senators to read. We have other committees where we are supposed to be voting today, as we wind up this week.

Mr. SCHWARTZ. I will do my best to summarize, and I appreciate your patience in the past, and I won't take advantage this time.

Senator HAWKINS. Surely. I thank you for coming.

Mr. SCHWARTZ. If I may, I would like to respond to one of the questions that Senator Kerry raised, and that you raised, as well, because I think it's very important.

One of our group's main concerns, as much as we hurt for the children that we have lost, or who are still with us but whose lives have been destroyed—as much as we hurt, we don't want a compensation program to come along and be enacted as a sop which doesn't bring about safer vaccines and safer administration of the vaccines.

We are pleased to have been able to work with the Academy of Pediatrics on this bill, and we are pleased that they have put out the notice that you talked about, to a point. But there is something very dangerous about that notice, and disturbing about it, and that is, it says, "If your child has high-pitched screaming or goes into a convulsion, call your doctor."

Well, "Call your doctor" is not the medical information that the American Academy of Pediatrics itself gives about such reactions. The AAP's Red Book says that if your child has a convulsion after a DTP shot, that's a contraindication. If the child has a high-pitched screaming reaction, that's a contraindication. The AAP's new document doesn't tell parents that, so they call their doctors, and their doctors—this has happened, we've gotten numbers of letters and phone calls—the doctor says: "Oh, it wasn't a convulsion, it wasn't related to the DTP shot. It was only your imagination. I didn't see it." Denial, repeated denial—we've heard that again and again.

And then the parent, not knowing any better, says, "Well, this is from the Academy of Pediatrics, this is what they said, I'll take my child in." The child gets another shot, and then the child may be permanently brain damaged.

That has happened, and that's why some of these court cases are coming. And I think, while I commend the Academy for moving in this direction, I wish they had consulted us, the consumers, about how this would be taken, and I wish they had taken steps to really warn about what are the contraindications.

The AAP's new parent information is a misleading document and a dangerous document, as well as the beginning of a beneficial move, and I think that needs to be known.

I think there are ways to better inform parents, and we would be happy to discuss that. And I appreciate Senator Hatch's kind comments about DPT's parent information packet.

I also want to say, and this is very important, although we have lost children, although others here suffer and have children who will suffer a lifetime of disability, we are not urging parents not to get vaccines. It is very important to us. We are not saying, "Get the shots." We are saying, "Get the information and make informed decisions." Some vaccines are safer than others, and that's very important. We want the parents to hear that.

We also want to say that it is a false dichotomy to say that the choice is between the existing vaccine program and no vaccine program. The existing vaccine program, you will be told, results in unavoidable injuries, and you will hear the claim that: "we are producing the safest vaccine we can and meeting stringent Federal standards.

The documents of the drug companies themselves, the Koehler memorandum, shows that 20 years ago the drug companies knew that the only safety test that existed—and this is contained in the appendices to our written testimony—the only safety test that existed was irrelevant for these kinds of effects. They knew that 20 years ago, and yet we have the same tests today. They claim, because they met that test, they're not negligent.

We have the same vaccine, and yet they didn't warn of the indequacy of the test—they didn't develop a safer vaccine, they didn't develop a more effective test, and you can see from the appendices to our written testimony that they know how to develop safer vaccines. It's in the literature. There's a 1982 symposium at HHS where Dr. Camerson says, "Sure, you can produce a much less toxic pertussis product in very low yields, and anyone who has worked on pertussis knows this. You can take out 90 percent of the junk that's in there that doesn't do any good and save the 10 percent that does." And this statement is not an isolated example.

So, we urge you not to think about a compensation program either in terms of either there being no vaccination program, or the one that uses the current unsafe pertussis vaccine.

We don't have to wait for star wars vaccines to come along; we could have been making safer vaccines all along. That's what we found out, and that's why we don't think it's appropriate to say: "Let's put blame aside."

Sometimes blame has to be assessed because that's the way we get change, by acknowledging responsibility, not denying it. We parents have the responsibility to know the truth about the dangers of these vaccines, and the doctors have the responsibility to administer them safely, and the manufacturers have the responsibility to produce them as safely as they can, and to warn when they can't, and to research to produce safer ones, and to use the best technology. And those responsibilities have not been met.

That's why these lawsuits are being settled and won, and that's why the documents are being concealed, and that's what has got to be changed, not swept under the rug.

We are very grateful to you, Senator Hawkins, for your leadership in these hearings, on this legislation, and insisting that the parents' rights be preserved, and we are very grateful for that.

We understand the need to assure adequate supplies of vaccine, and that's why we agreed to support a backup insurance authority in this legislation, if needed in genuine emergency situations.

But we warn you that you will hear from all kinds of experts today. Those same experts told you to support the Swine Flu Program, and I think it's worth noting the quote here that we've found, which is from someone who studies experts; he says, "An expert is a person who avoids the small errors while sweeping on to the grand fallacy." And these experts may be able to tell you what the correct delta is for this statistic and that statistic, but the point is, we've got a lot of needlessly injured and dead children, and we're going to have more unless we take steps now at all of these different levels.

We think the administration approach is shocking and shameful, because it fails to take any responsibility for developing safer regulatory programs for these vaccines, and pretends we have a fine program. And it's shocking and shameful because the administration approach fails to gather any data on vaccine reactions or to inform parents; and it's shocking and shameful because all it does is take away existing rights of parents without offering any new alternatives.

And the one new opportunity that's offered by the administration is another study. They had the 1975 study, they had the 1978 study, they had the 1981 study. You asked them in 1982 to do a study; they had the 1983 study, and the result of the 1983 study is: "We're studying it." Now, they propose a 1985 study.

I think that's enough, and I hope the committee will think that that's enough.

We appreciate your patience; and we urge you, as you listen to the remainder of the witnesses, to listen to their perceptions—not as fact, but as perceptions, and then test these claims against the facts. Is it really true that the injuries are unavoidable? Was there really a shortage, or was it manipulated by a manufacturer who chose to keep 3 million doses off the market in the face of an apparent need in order to try and bludgeon this Congress into giving indemnification from liability?

We ask you to look at these questions hard, particularly: "Is this really the safest vaccine that can be produced?" We ask you not to accept the manufacturers' claims at face value, because if you accept those assertions uncritically you will not have been, in our view, living up to the promise that Senator Hatch gave of legislating in the light.

This book, "DTP: A Shot in the Dark," is a guide which is so important it must be reckoned with. It must be read, and the questions raised in it must be considered, as well as all the other questions we've raised in our testimony.

We have been willing to compromise. We compromised initially with the Academy in the drafting of S. 2117 in the last Congress. We have made more compromises in S. 827, but we expect others to compromise, as well, and there is some point at which, perhaps, compromise goes too far.

We have already been told by the trial lawyers and the National Health Federation and other parents groups, they think that we, perhaps, have gone too far in trying to reach accommodation. We are willing to make compromise, to a point, but we cannot compromise justice, and we cannot compromise the truth.

And we urge this committee, Senator Hawkins, to follow the very wise counsel of Senator Stafford, and the others who have insisted that nothing we do here take away from the responsibility of the manufacturer to produce safe vaccines, as safe as possible, and doctors to administer them safely.

It's not cost effective, it's not conscientious, it's not just to allow preventable injuries to occur when they don't have to.

Thank you for allowing a summary; I ask that this material be submitted for the record. We also ask, on behalf of other parents who could not be here today, to be able to submit for the record, and with your permission, Senator Hawkins, I would like to indicate that there have been parents from all across the country who have traveled here today, at their own expense, even without any orchestrated campaign by us--in fact, we tried to discourage them from doing that, for a variety of reasons, but they insisted on coming. With the committee's permission, I would at least like the parents of children, who are here, who have been injured or killed by the vaccine, to have a chance to stand up so that you can see them.

Senator HAWKINS. Surely.

Would those parents who have gone through this, would you please stand up.

[Sixteen people stand.]

Mr. SCHWARTZ. Thank you.

[The prepared statement of Mr. Schwartz and responses to questions submitted by Dissatisfied Parents Together, along with additional material, follow:].

Dissatisfied Parents Together (DPT) 128 Branch Road, Vienna, VA 22180 (703) 938-DPT3

TESTIMONY BEFORE THE U.S. SENATE
COMMITTEE ON LABOR AND HUMAN RESOURCES

July 18, 1985

Jeffrey H. Schwartz, President
Dissatisfied Parents Together (DPT)

Mr. Chairman and Members of the Committee:

My name is Jeffrey H. Schwartz. I am President of Dissatisfied Parents Together (DPT) and am here on behalf of that group. DPT has been in existence since April 1982, and since that time we have responded to over 12,000 requests for our information booklet on pertussis and pertussis vaccine, as well as countless other inquiries and expressions of concern. These have come not only from parents and grandparents of children injured or killed by childhood vaccines, but also from parents of healthy children, doctors, nurses, immunization clinics, school boards, state legislators and state health departments. We make no pretense of representing all parents -- or even all parents of injured children, but we know that the concerns we raise are ones that have been voiced to us thousands of times in the past three years.

Mr. Chairman, I want to thank you for convening today's hearing and for scheduling the three previous hearings on this important subject. I also want to express DPT's thanks for allowing us to testify today and for your co-sponsorship of S. 827. While we recognize that you may not support every aspect of the bill, your general support -- along with Senator Hawkins' leadership on this issue -- has helped turn the spotlight on this pressing problem. We are perhaps grateful most of all for your pledge that "we will not legislate in the dark" when vaccine safety and compensation bills are considered.

A. DPT's Position on the Legislation

Unfortunately, the story you have just heard Denise Judd tell is not unique. I only wish it were. But today Julie is dead, and so are Adam, Amber, Bernadette, Bronson, John Stuart, Kara, Lee Ann, Richie, Stevie and so many other children killed by childhood vaccines. Many hundreds more live out their days in courageous misery -- brain damaged, wracked with seizures, crippled, learning disabled, neurologically impaired -- all as a result of the vaccines we gave (and the government recommended) to protect them.

We understand the limited time available for this hearing and regret that the schedule does not permit a complete telling of the children's stories. If the Committee entertains doubts as to the depth or breadth of this problem, we urge it to arrange an "open hearing" at which parents can relate their family's experience with vaccine reactions.

Despite our own experiences, we are not an anti-vaccine group. Our three major goals are simple. We seek to prevent other children and families from suffering the catastrophes that have befallen us. We seek the preservation of existing rights and the creation of new alternatives to better care for the children who are damaged by these state-mandated vaccines. And we seek the truth. We seek all this with due regard for the importance of appropriately structured disease prevention programs.

These goals are the reasons why we helped develop and are supporting S. 827. We are proud to join with a number of medical, nursing, provider, public health, consumer, and other groups in supporting this bill. For this bill would do what no other bill that has been discussed would do:

* require safer vaccines, and impose stronger standards of care and mandates for vaccine testing, warning, labeling, quality control, field surveillance, and recall for the FDA and the manufacturers;

* provide both doctors and parents with the information necessary to elicit and give genuine informed consent;

* require reporting, recording, and long-term follow-up of major vaccine reactions, so that we can really know how many deaths and how much long-term damage is actually attributable to mandated childhood vaccines;

* preserve parents' unfettered access to the tort system, both to permit parents to choose the legal care that we think is most appropriate for our injured children, and to retain the tort system's deterrent incentives against negligence (and defective or unreasonably dangerous vaccine formulations) in the manufacture and administration of mandated vaccines;

* offer an expeditious, non-adversarial, unbiased and adequate compensation alterantive to the tort system for those parents who elect it; and

* provide emergency stand-by authority for HHS to assure adequate supplies of childhood vaccines if private insurance genuinely becomes unavailable to vaccine makers.

As the side-by-side comparison (attached as Appendix A) indicates, S. 827 meets these goals, while neither the Madigan-Lederle bill (H.R. 1780), nor the draft Administration bill (see Appendix B) would come close. In fact, the Lederle-Madigan bill and the Administration's reported approach would discriminate against this one class of victims by limiting damages and access to the tort system. This is a sorry way to treat those who deserve special care for having been damaged or killed by the only product mandated by law and so inadequately regulated by HHS.

As drafted, for example, the Lederle-Madigan bill would allow no compensation to the Judd's for the death of Bronson, not even burial expenses. Thus we support S. 827 and strongly oppose H.R. 1780 and the Administration's reported approach.

B. Legislating in the Light: Exploding the Myths of "Vaccine Safety"

We know that much of the focus by others testifying today will be to seek weakening changes in S. 827 or to oppose it outright. But we would like to point out that this bill already represents a number of substantial compromises. S. 2117, the predecessor of S. 827 in the last Congress, was the product of compromise between Dissatisfied Parents Together and the American Academy of Pediatrics. In order to respond to critics of S. 2117, this year's bill incorporates a number of changes: limiting compensation to those with long-term (over one year) injuries or death cases; narrowing the presumptive table of compensable events; authorizing federal back-up insurance to assure vaccine supply availability; and precluding awards based solely on the vaccine manufacturer's duty to warn parents directly.

Those who oppose S. 827 will say that Congress must go further toward protecting vaccine makers and doctors, and take away existing rights of vaccine-injured children. These positions will be justified by the various speakers portrayal of what the problem really is, and what áre the appropriate solutions.

But before Congress can craft a proper legislative solution, it must correctly define the problem. The Committee must sort out conflicting perceptions:

* According to HHS, there is no serious problem and certainly no legislation appears to be required (except perhaps to curtail punitive damages and pain and suffering awards in court).

* According to the vaccine manufacturers, they have produced the safest vaccines science will allow and have complied with FDA regulations. Thus they believe they are not at fault and should not be subject to tort suits. They argue that they cannot remain in the market if they face the uninsurable risks of lawsuits, and thus urge Congress to preclude or limit access to court and damages which may be awarded.

* The AMA has argued that even vaccine injuries caused by the gross negligence of doctors should not be the basis for lawsuits by parents. They have also implied that without protection against parental suits for violating drug company warnings and official contraindications, doctors might be unwilling to remain part of the vaccine program.

* We parents dispute these premises and also the conclusions based on them. So do most of the groups which have joined with us to support S. 827.

Congress cannot merely passively rely on the assurances of the "experts" that the benefits of all childhood vaccines exceed their risks. The experts' advice that led to the "swine flu fiasco" should serve as a warning of their fallibility. For as one commentator reminds us, "An expert is a person who avoids the small errors while sweeping on to the grand fallacy." Rather than uncritically accepting the experts' opinions, Congress must search out the truth for itself.

We believe the facts will speak for themselves, if only they are brought to light. But there is a problem: the vaccine manufacturers have used threats, scare tactics, deceit, and concealment to try to keep the facts from Congress, concerned physicians and parents, and the American public. Those facts that have come to light in the last three years suggest a reality far different from the rosy picture painted by HHS and the manufacturers. Consider, for example, the following "myths" and "facts":

Myth #1: The pertussis vaccine is basically safe, since it passes the government "safety test." Manufacturers of the vaccine thus are not negligent and should not be held liable for "unavoidable" injuries.

FACT: In 1964, representatives of the pertussis vaccine manufacturers met and acknolwedged that the only safety test (known as the "mouse toxicity test") used for the pertussis vaccine is "essentially irrelevant" for measuring the propensity of a specific lot of vaccine to cause severe neurotoxic reactions. In other words, the test is basically worthless. This meeting is summarized in the "Koehler memorandum" (Appendix C, emphasis added).

FACT: So far as we are aware, the drug companies failed to warn the FDA, doctors or the public of the ineffectiveness of the so-called "safety test" in the 21 years since that meeting. Apparently they failed to research and develop more reliable safety tests, and so did the FDA. Not until the early 1980's did any U.S. manufacturer seriously begin research on acellular vaccines.

Questions: The drug companies need to be asked directly by Congress --

1. Whether the Koehler memorandum accurately reflects their understanding as of 1964 and since that time?
2. Whether they advised the FDA of the irrelevancy of the "safety" test, and if not, why not, since this was the sole "safety" test they had to pass to get their vaccine onto the market?
3. Whether they advised doctors or the public about the irrelevancy of the so-called "safety" test, and if not, why not?
4. Whether they made any effort since 1964 to develop an effective safety test, and if not, why not?
5. What exact efforts did the companies make since 1964 to develop safer extracted and acellular vaccines?

In other words, what have the drug companies been doing for the past 21 years since they realized that the FDA "safety test" was not a safety test at all? What does their action or inaction say about their truthfulness and good faith?

Myth #2: Today's U.S. whole cell pertussis vaccine is the best vaccine available.

FACT: In the 1960's, Lederle tested the reaction rate of its vaccine as compared to the then-produced Lilly pertussis extract vaccine. A 1967 internal Lederle memorandum states that Lederle's vaccine produced more adverse reactions than the Lilly vaccine (Appendix D). Yet when questioned by doctors about the comparative reactivity of the Lilly and Lederle vaccines, Lederle stated falsely that there was essentially no difference between the two vaccines' reaction rates (Appendix E).

FACT: In the 1982 HHS confidential symposium on pertussis vaccines, a medical advisor to one of the vaccine makers stated, "I would agree with what Dr. Cameron said, that sure you can produce a much less toxic [pertussis vaccine] product in very low yields, and anyone who has worked on pertussis knows this, you can get a little bit out -- maybe ten percent which is active and you throw the rest away." (Appendix F, emphasis added);

FACT: A 1983 Pediatrics article concluded, "Although the whole cell [pertussis vaccine] is the most commonly used in the United States, it is clearly the most reactogenic in terms of common reactions... Until [a new generation of pertussis] vaccines are available, a sufficiently antigenic, yet less reactogenic vaccine might be prepared from the components now available." (Appendix G);

FACT: In a 1983 report, the National Institute of Allergy and Infectious Diseases stated, "Using newer technology an acellular vaccine has been developed in Japan and is in general use there. Preliminary reports from Japan indicate that the vaccine is effective and relatively free of side effects." (Appendix H).

Myth #3: Only one pertussis vaccine maker remains in the market today. Other companies have been driven out of production by the lawsuits and inability to get insurance.

FACT: As of the date of this hearing, there are three private producers of DPT vaccine (Lederle, Wyeth and Connaught), just as there were three producers on the date of the last hearings on this bill. (This does not count states who produce DPT vaccine.)

FACT: Wyeth announced in June 1984 that it was "leaving the market", but in July 1984 it silently entered into an agreement with Lederle that it (Wyeth) would resume production of vaccine, and Lederle would market all Wyeth's DPT production. Thus vaccine now marketed under the Lederle label represents the combined production capacity of two companies, Lederle and Wyeth.

FACT: Connaught, after threatening in December 1984 to withhold its 3 million dose stockpile from the market -- stating that it could not get insurance and demanding a legislative grant of immunity from lawsuits -- by May 1985 had apparently obtained insurance and quietly "re-entered" the vaccine market.

FACT: Congressman Henry Waxman's Health Subcommittee is investigating the cost and availability of liability insurance to pertussis vaccine manufacturers. Any representations made by the companies before this Committee should be carefully compared with answers obtained by Congressman Waxman.

Questions: Congress needs to ask the drug companies and HHS--

1. Why the apparently phony "vaccine shortage" scare of this past winter was allowed to frighten the American public?

2. Why, if Connaught can get private insurance, is there a great pressing need to preclude tort suits?

3. What have the insurers told vaccine makers about the insurability of Lederle's legislative proposal (H.R. 1780)?

Many more myths abound. Among these "myths" are:

- that only a few children suffer long-term injury;
- that these injuries are simply unavoidable accidents, with no negligence or bad batches;
- that the children who die shortly after getting DPT shots are all "SIDS" deaths, not vaccine reactions;
- that the increased costs of vaccine are entirely attributable to the lawsuits;
- that HHS expert panels would be unbiased arbiters of vaccine injury claims;
- that the cost of compensation under the Lederle approach would not be passed on to the public in the form of higher vaccine costs, etc.

Time and space unfortunately prevent us from providing all the facts here that rebut these "myths." But the previous examples illustrate the half-truths and smokescreens that have characterized the drug companies efforts to "enlighten" the Congress. These examples point up why it is so critical for Congress "not to legislate in the dark."

In addition, we urge the Committee to take particular note of, and inquire about:

1. The threats of Lederle to --

    a) withdraw from the market in California if the state's legislature passed a bill requiring the company to accurately label the actual potency of its varying vaccine lots; and

    b) withdraw from the U.S. market altogether if the U.S. Court of Appeals for the Ninth Circuit upheld the federal district court's $1.4 million verdict against it in the Toner case.

2. The refusal of all three pertussis vaccine makers to appear on the 20/20 show on DPT vaccine, coupled with the attempt made by at least one company to get ABC to suppress the show; and

3. The drug companies' repeated pattern of concealing critical documents through sealed settlements and protective gag orders which deny the public and the Congress access to the truth.

If the drug companies really do not bear any fault and have nothing to hide, as some have claimed, why won't they open their files to Congress, the press and the public?

Before any consideration is given to eliminating all punitive damages, as the Administration evidently is prepared to propose, or to cutting off or limiting lawsuits even for gross negligence, as the AMA and Lederle propose, respectively, we believe Congress needs to ask the foregoing questions.

The disturbing reports of Advocates for a Safe Vaccine; Physicians for the Study of Pertussis Vaccine; 20/20; Gannett News' "Vaccine Machine"; the Fresno Bee; WRC-TV's "DPT: Vaccine Roulette?"; Science magazine and many others raise additional questions that deserve to be answered.

We particularly urge this Committee to examine carefully questions raised in DPT: A Shot in the Dark by Harris Coulter and Barbara Fisher. How could the fifty year record of warnings in the medical literature about the dangers of pertussis vaccine (see Appendix I) be so ignored by the vaccine makers and by the FDA? DPT: A Shot in the Dark sheds some important light on the foregoing questions. And so do the other investigative reports mentioned above. The lawsuits themselves have helped bring the facts to light. But only Congress can ultimately get the full answers.

C. A Time to Decide

In making its decision on this legislation, we ask the Committee to consider the following criteria:

- A compassionate government would leave no stone unturned to care for the children and families that the government's own policies and mandates have so damaged. It would not turn its back in indifference.
- A cost-effective government would count improved vaccine safety measures and safer vaccines as among its highest priorities. It would not remove or limit incentives for greater care to prevent avoidable injuries and death.
- A candid government would admit the weaknesses as well as the strengths of its programs and seek to remedy, not deny, them.
- A non-coercive government would educate and persuade its citizens as to the best ways to care for our children's health, not depend on threats and sanctions, fear and duress.
- An accountable government would assure that the governmental agencies, physicians and drug companies responsible for the immunization program are answerable to the Congress, the courts, and the public, and are held to the highest standards of care.

So now it is time for this Committee to decide. What kind of government has HHS been on the issue of vaccine safety and compensation? What kind of government will we choose for the future?

The record of HHS on vaccine safety and compensation has been a public shame and a private sorrow.

1. Why has it failed to adopt anything but "minimal" vaccine safety standards, as recognized by the Second and Eighth Circuit Courts of Appeal in the Tinnerholm and Stromsodt cases? Why has it failed even to enforce these "minimal" standards?

2. Why has HHS been studying the compensation issues and options for more than eight years without issuing a single recommendation?

3. Why has it totally excluded parents of vaccine-damaged children from these studies and from its deliberations on legislative recommendations?

4. Why has HHS failed to push for safer pertussis vaccines for the more than 30 years since Byers & Moll's famed 1948 call for safer vaccines?

5. Why has HHS failed to require manufacturers to limit the pertussis toxin, to exclude endotoxins, and to provide accurate potency labeling and adequate warnings for the vaccine?

6. What did HHS know, when did it know it, and what was its responsibility to know and act in this area?

Is it any wonder parents of vaccine-damaged children strenously oppose recommendations such as those made by the AMA and Lederle, that would put HHS-approved panels in charge of making decisions as to the compensability of vaccine injury claims? HHS' cost containment and immunization promotion responsibilities, its insensitivity to the dangers of vaccines, and its political subjugation to OMB create institutional conflicts of interest which make the Department a biased and unacceptable arbiter of vaccine injury claims and damages.

Unfortunately, until this Committee's hearings, Congress has not overseen the Health and Human Services Department's vaccine safety program, nor directed HHS to prevent needless vaccine injuries and deaths as well as communicable diseases. The granting of broad authority to do right is not enough. Vigilance and rigorous oversight by the Congress are required. For, as Justice Renquist wrote earlier this year in his Heckler v. Chaney decision:

> The danger that agencies may not carry out their delegated powers with sufficient vigor does not necessarily lead to the conclusion that [reviewing] courts are the most appropriate body to police this aspect of their performance. That decision is in the first instance for the Congress...[53 U.S.L.W. 4385, 4388 (1985)]

So now it is time for this Committee to decide. We urge you to shine the light in all the dark corners, demand to see the secret documents which the vaccine makers have kept hidden, ask the hard questions and insist on answers that correspond to the facts. When this is done, we know the pledge "not to legislate in the dark" will have been honored. And we can rest easier in the knowledge that, as parents, we have done all we could to protect the future's children, to care for our present children, and to honor the children we have loved and lost.

Dissatisfied Parents Together (DPT) 128 Branch Road, Vienna, VA 22180 (703) 938-DPT3

Appendix A

INDEX

The attached table compares the vaccine safety and compensation bill introduced by Senator Paula Hawkins (R-Fl) and with that introduced by Congressmen Edward Madigan (R-Il) and James Broyhill (R-NC). The topics listed are compared at the pages indicated.

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The Hawkins bill was developed by Dissatisfied Parents Together (DPT) and the American Academy of Pediatrics and is supported by:

The American College of Physicians
The American Public Health Association
American Nurses Association
Association of Retarded Citizens
Association of Schools of Public Health
Association of State and Territorial Health Officers
Association of Teachers of Preventive Medicine
Epilepsy Foundation of America
Health Department of the State of Michigan (a vaccine manufacturer)
National Association of Children's Hospitals and Related Institutions
National Foundation on Birth Defects (March of Dimes)

Dissatisfied Parents Together (DPT) 128 Branch Road, Vienna, VA 22180 (703) 938-DPT3

COMPARISION OF VACCINE SAFETY
AND COMPENSATION BILLS

Issue/ Subject	Existing System & Law	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Promotion of Safer Vaccines -- Improved Testing, Warning, etc.	FDA is vaccine licensing entity; no affirmative duty on government to assure development of safer vaccines.	Creates affirmative, enforceable duty for HHS to promote development of safer vaccines, better testing, warnings, etc. Authorizes citizen suits to compel HHS to act to carry out these requirements.	Creates similar though less extensive directive to HHS. But this directive is not enforceable. No citizen suit authority or other sanction if the Secretary fails or refuses to meet these obligations.
Parent Information	Private physicians aren't required to give any information to parents on risks of vaccines & contraindications; public clinics are supposed to give information, but the so-called "important information" forms are inadequate and misleading.	Requires both public and private health care providers to give written information to parents before mandated shots are given. The information must explain which children should not get a shot or should delay getting shots. Requires listing of potential severe reactions and appropriate parental precautions & responses.	Same.
Reporting & Recording of Severe Reactions by Health Care Providers	The existing system has no mandatory recording or reporting of severe vaccine reactions by private physicians. No mandate for recording of vaccine manufacturer & lot number. The present voluntary recording and reporting system makes it nearly impossible to derive credible risk-benefit figures.	Mandates recording & reporting of major reactions to mandatory vaccines. Also requires doctors and clinics to record manufacturer & lot number of vaccines given. These requirements are important to implement an effective field surveillance and recall program (see below).	No comparable provision.

Issue Subject	Existing System & Law	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Reporting & Recording of Severe Reactions (continued)	Failure to record severe reactions on patient's chart also increases risk of later injury to child from vaccine & denies child the opportunity to seek compensation.		
Field Surveillance and Recall of Bad Batches or Lots of Vaccine	Manufacturer field surveillance and follow up of adverse reactions is almost non-existent. This appears acceptable to HHS (see p. 130, Sen. Hearings, 5/3/84).	Mandates improved field surveillance and follow-up of reported reactions to determine severity and duration of reactions and assess the need for recall by HHS.	No comparable provision.
	HHS has no authority to require recall of biologicals under current law.	Authorizes HHS to institute mandatory recall of excessively reactogenic batches or lots of vaccine. Makes violation of a recall order punishable by a civil penalty of up to $100,000 per day.	No comparable provision.
	Without effective record-keeping & reporting requirements, recalls of bad batches or lots would not be practical in any event.	Also requires HHS to notify manufacturers of severe reactions to their product, so that manufacturers could take voluntary recall actions where warranted.	No comparable provision.
Manufacturer Record-Keeping & Reporting of Production Problems, Testing & Distribution of Vaccines	Under present law and practice, HHS does not require vaccine manufacturer record-keeping or reporting of vaccine lot production problems, failed toxicity test results, repooling or reworking of vaccines, or of vaccine distribution patterns.	Mandates adequate record-keeping and reporting to HHS by vaccine manufacturers of production problems, toxicity test results, repooling and reworking of vaccines, and maintenance of adequate vaccine distribution records. Makes effective recall of bad batches or lots a real possibility.	No comparable provision.

Issue/ Subject	Existing System & Law	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Manufacturers' Record-Keeping & Reporting (continued)	Under current law, reactogenic lots can reach the market without HHS awareness or special review. Even voluntary recall of problem batches or lots becomes virtually impossible with HHS' current grossly inadequate requirements for manufacturer record-keeping and reporting.	Also assures better pre-release surveillance of vaccine safety by HHS.	No comparable provision.
Review of Adequacy of Warnings	HHS provides only ad hoc review of manufacturer warnings and contraindications. On several occasions, HHS has discouraged or even prohibited warnings sought by manufacturers.	Mandates HHS to undertake systematic review of adequacy of vaccine manufacturer warnings and use instructions for all mandated vaccines. Requires determination within 18 months as to adequacy of warnings. Warnings found inadequate must thereafter be revised.	No comparable provision.
Public Accountability	Most vaccine policy is made behind the scenes in publicly unaccountable ways -- no rulemaking, no judicial review.	Requires major elements of vaccine policy to be made by rule, with public notice and right to comment, and subjects HHS vaccine rules to judicial reviewability.	No comparable provision.
	If HHS fails to carry out a duty under the law, there is no effective enforcement mechanism. Parents are effectively foreclosed from obtaining court review of HHS action or inaction on vaccine safety issues.	Authorizes citizen suits to compel HHS to carry out legal requirements for vaccine safety. Authorizes the courts to permit reasonable attorneys' fees and costs in appropriate cases, thereby enabling parents who otherwise could not afford it to get access to the courts in cases raising important public policy issues regarding vaccine safety.	No comparable provision.

Issue/ Subject	Existing System & Law	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Compensation for Vaccine-Related Injuries: Basic Framework	Tort System Only right to sue drug company or doctor for damages; no compensation system is available.	Parental Elective System: Parent would have right either to sue drug company/ doctor under existing state law, or use alternative compensation system, but not both.	Victim Rights Restriction System: Takes away rights of damaged child and parents to sue doctor or drug company directly. Gives right to drug company to decide whether child must first enter the inherently biased "compensation" system which the bill establishes. Drug company has the right to opt into this compensation sytem, but parent or child does not have the right to opt out and seek damages in court under state law directly.
Standard & Basis for Compensation	No compensation system provided.	If a claimant is found to be eligible for compensation, then payment of appropriate damages is mandatory.	Payment of any compensation would be entirely discretionary for the panel, even in the case of a child found to be severely injured by a mandated vaccine.
		Compensable damages include:	Compensable damages include:
		- health, education, rehabilitation and custodial care expenses necessary for child to achieve "maximum feasible potential and enjoyment of life";	- similar, but absolute cap of $1 million placed on all compensation, regardless of needs of the child;
		- $300,000 - $700,000 for a child's death;	- no compensation provided for children killed by vaccines, not even burial expenses.

Issue/ Subject	Existing System & Law	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Standard & Basis for Compensation	No compensation system provided.	Compensable damages (continued) - anticipated loss of earnings when child becomes an adult; - pain and suffering for child only up to $100,000; and - other vaccine injury-related expenses.	Compensable damages (continued) - similar, but again subject to total $1 million cap on all compensation; - same, but again subject to total cap on compensation; - no comparable provision;
Ceiling on Allowable Compensation	For tort law purposes, ceilings on allowable recoveries are established by state law. No compensation system is provided.	The only ceiling on compensation would be the amount necessary to meet the needs of the child, plus a limit on pain and suffering awards and on death benefits. DEpending on how severely retarded and disabled the injured child is, care and education expenses alone may currently exceed $10,000/month. No federal ceiling is provided on state tort suit damage awards.	An absolute ceiling of $1 million is established for both compensation and tort law damage awards, regardless of the needs of the child or the degree of fault of the drug company or administering physician Since no reimbursement for costs or expert witness fees is authorized and since payment for attorneys' fees comes within the ceiling, the effective compensation ceiling for the injured child may be more like $450,000 - $600,000. This absolute ceiling applies to both the compensation program and any tort law suit damages.
Punitive or Exemplary Damages	Under most state laws, exemplary damages can be awarded in cases of gross negligence, reckless disregard for the health and safety of others, or fraud. Purpose is to deter such wrongdoing	No punitive or exemplary damages would be authorized in the compensation system. No change in state tort laws would be provided in this respect, i.e., exemplary damages would be allowed to the extent and under the circumstnaces permitted by state tort law.	No punitive or exemplary damages could be awarded under either the compensation system or the state tort system, no matter how grossly negligent, reckless or fraudulently the vaccine manufacturer or doctor has acted. Thus a significant incentive for exercising care in vaccine manufacture, testing, etc. is abandoned.

Issue/ Subject	Existing System	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Lawyers' Fees	Fees may be 33-50% of total award in tort suit; costs may be $50,000 or more. Both come out of the amount awarded to the injured child.	Compensation system directs payment of "reasonable attorneys' fees" up to 20% (25% if appeal is taken), but this does not reduce the child's compensation.	Reasonable attorneys' fees (but not costs) may be awarded. However, these too are subject to the total compensation cap. Thus the chld's award could effectively be reduced by 25-50% or more. "Reasonable" attorneys' fees (and other costs) could be higher under a mandatory adversarial compensation system, which would have to precede any tort litigation.
Nature of the Process	Tort suit involves adversarial process.	Compensation system offers a non-adversarial alternative to tort suit -- although claim must be corroborated and expert witnesses may be called by special master or judge.	Compensation system is less formal than tort suit, but basically adversarial.
		No drug company or doctor need be charged by the claimant as having caused the injury. Thus a claim for compensation may be brought successfully, even when the identity of the specific manufacturer is not known.	Claimant must name responsible drug company and doctor. If for any reason these are unknown, deceased or insolvent, claimant may have no compensation remedy.
Who Decides Whether to Compensate and How Much	No compensation system	Federal judge on the advice of an expert (special master) appointed by federal judges. Thus no new bureaucracy is necesary. Also judges are politically independent; not accountable to HHS or OMB; not subject to conflict of interest. Only duty is to find the truth, carry out the law, and provide "simple justice for children." Referral of all claims to DC federal district court assures consistency of treatment of claimants.	Eleven regional "expert panels" to be drawn from list established by HHS. Since HHS controls who goes on the list and who stays on the list of approved experts, prospective panel members are subject HHS political control. HHS' involvement, its interest in containing health care costs and promoting immunizations, and its failure to acknowledge the severity of the vaccine reaction problem makes this system inherently biased against claimants.

Issue/ Subject	Existing System & Law	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Statute of Limitations	No compensation system.	Claim must be filed within five years of occurence of injury or two years after date of bill's enactment, whichever is later. This limitation does not apply if claimant did not receive the required parent information packet or did not know the injury was compensable.	Claim must be filed within 2 years after first manifestation of injury or 2 years after the date of enactment, whichever is later. This limit applies regardless of when claimant discovered the causal link between the injury and the vaccine.
Deadlines for Compensation Decision	No compensation system.	270 day deadline for district court decision; any appeal to be expedited.	No deadline for action by compensation panel, so process could be lengthy and needed compensation for child could be delayed.
Criteria of Eligibility for Compensation	No compensation system	A child must have been killed or had at least one year of residual effects or complications to be eligible for compensation. The bill establishes a table of presumptive compensable events , based on AAP recommendations, HHS-funded studies, the National Childhood Encephalopathy Study, the OTA report, and other medical literature. The table may be revised by HHS in a rule-making procedure. The claimant may also recover if he/she shows that the injuries were caused by a mandated vaccine, without reliance on the presumptive table.	No presumptive criteria for compensable events are established in the bill. THus there are no guidelines to assist panels in determining whether or not various injuries are caused by vaccines. This increases the risk of inconsistent and inequitable treatment of similar situations.
Vaccines Covered	No compensation system.	Compensation system is available only for dealing with the presently generally mandated vaccines: DPT, OPV, MMR.	Compensation (& tort limits) could be applied to any vaccine listed by HHS, as well as presently mandated vaccines.

Issue/ Subject	Existing System & Law	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Who Pays Compensation Awards	No compensation system.	Compensation awards would be paid from a special fund -- the revenue source for which would be a vaccine surcharge. The surcharge would be collected initially from vaccine manufacturers, but passed along ultimately to vaccine consumers and purchasers.	Compensation awards would be paid by named vaccine manufacturers initially. As in the past, however, these costs too will be passed through to vaccine consumers and purchasers.
Physician Liability	No compensation system.	Compensation awards would be paid as described above. Physician could be held liable under the compensation program only if the US govt. could show the doctor was negligent in administering the vaccine.	Any doctor who opts into the system could be held "jointly and severally" liable for the claimant's entire damage payment, if no fault can be established on the part of the vaccine producer.
Insurance Availability and Vaccine Supply Assurance	Under current law, the government has no authority to provide any insurance, reinsurance, or pooling arrangements for producers of mandated vaccines.	The Secretary of HHS would be authorized to provide for pooling arrangments, reinsurance, or direct insurance, if necessary to assure availability of mandated vaccines (at reasonable prices), and if such insurance would not be available from the private sector otherwise. The authorities are discretionary, not mandatory, and may be used under such terms and conditions as the Secretary requires. These authorities would have to be implemented in a way so as not to undercut the incentive for development and use of safer vaccines.	No comparable provision. The authors maintain that the caps on damage awards will make the vaccine market insurable through the private sector. But this assumes that the total number of injured claimants can be predicted accurately and the damage award limits on state tort law are constitutional -- both propositions being open to question.

Issue/ Subject	Existing System & Law	Hawkins/AAP/DPT Bill (S. 827)	Madigan-Broyhill Lederle Bill (HR 1780)
Override of State Tort Law/ Impairment of Claimants' Rights Under State Law	Tort law governed by state law and policy.	Parent would have to elect between compensation option and tort suit. If parent elects compensation system, then no tort suit may be brought. No tort liability may be based solely on manufacturers' failure to warn parent (or vaccinee) directly. Otherwise, no override of state tort law or impairment of claimant's rights.	State tort law would be overridden in the following ways: - no punitive damages could be awarded in any vaccine injury case; - no damages may be paid in state tort suits for a child killed by a mandated vaccine, not even burial expenses. - absolute cap of $100,000 imposed on state awards for child's pain and suffering; - absolute cap on toatl award of compensatory damages in state tort suits; - federal exhaustion of remedies requirement would be imposed; no state suit could be filed unless federal compensation system had been tried first; - more restrictive statute of limitations would be imposed on many states; since being barred from the federal compensation system on statute of limitations grounds can keep claimant out of state tort system, the federal statute of limitations effectively overrides more lenient state statutes; - state evidentiary rules would be overridden as well as state legal presumptions, since federal compensation decision would be admissible in any tort suit and "presumed correct."

Appendix B

Inside the Administration

An exclusive report on the Reagan Administration's economic, regulatory and management policies

DRAFT REAGAN VACCINE BILL POSES UNPRECEDENTED BAN ON PUNITIVE DAMAGES

The White House Cabinet Council on Human Resources working group on vaccine supply & liability has drafted a bill, obtained by *Inside the Administration* and reprinted here, that would impose an unprecedented ban on punitive damage awards and would limit awards for "pain and suffering" to no more than $100,000 in cases where manufacturers are found liable for death or injuries to innoculated children. The bill, which sources have said will run into "political disaster" on Capitol Hill, was drafted to head off what the Administration sees as objectionable new legislation to establish a compensation program for injured children, according to a "highly confidential" internal White House memorandum also reprinted here. Administration sources maintain that the bill will provide just compensation to children and their families, as well as ensure the availability of vaccine supplies by removing the possibility of "astronomical" awards that have been "scaring off" both insurers and manufacturers in recent months.

The draft legislation would limit damages for injuries or death caused by federally approved vaccines for seven communicable childhood diseases, including diphtheria, pertussis, tetanus, poliomyelitis, measles, mumps, and rubella. Sources note that the legislation ultimately would limit the liability of federal and state governments as well as manufacturers and insurers, since liability potentially could be traced back to the Food & Drug Administration for approving the vaccines, and to the states for mandating innoculation.

In explaining the need for legislation, documents note that "the unpredictability and size of claims for punitive damages and non-economic loss have made insurers unwilling to provide adequate coverage to vaccine manufacturers for vaccine related claims. Without this coverage, the supply of needed vaccines is threatened because vaccine manufacturers are unwilling to bear the financial risks involved in continuing to produce and distribute the vaccines." Documents also assert that "the elimination of punitive damages and a uniform national limitation on damages for non-economic loss is necessary to assure the continued availability of needed childhood vaccines. . . .Punitive damages and unlimited damages for non-economic loss are not needed to provide equitable compensation to individuals who have suffered from vaccine side effects."

Congressional sources maintain there is "no political support" for the Administration proposal, because it appears to penalize injured children and their families while helping manufacturers avoid liability. Bipartisan support is growing in the Senate for legislation which would establish a federally sponsored compensation program to help children — a development which the White House memo notes with consternation. Administration sources acknowledge that their bill sets a radical new precedent for limiting damages in state and federal tort cases, but they argue that the bill responds to a "unique" situation and need not be applied broadly. Similar proposals to cap awards in Congress have been designed to encourage the use of administrative remedies, and almost always have been coupled with compensation schemes.

CABINET COUNCIL PROPOSAL FOR LEGISLATION GOVERNING CHILD IMMUNIZATION

SUBJECT: The Cabinet Council on Human Resources Working Group on Vaccine Supply and Liability

There have been a series of news reports recently concerning childhood immunization and the availability of vaccine in the near future. Concern about liability for adverse side effects of immunization is one of the central issues at hand.

The last Congress considered bills that would have established an immunization injury compensation program. For a number of reasons, the Administration opposed these bills. There will be related proposals this year.

The Chairman Pro Tempore of the Cabinet Council on Human Resources has approved establishing a Cabinet Council Working Group on Vaccine Supply and Liability to undertake a review of these issues. This study should include an assessment of the adequacy of the supply of vaccine, both near-term and longer-term; the cost of vaccine, now and in the future; the nature and incidence of adverse reactions to vaccine; the liability and insurance problems of producers and providers of vaccine; proposed solutions to vaccine-related problems; and recommendations for the Administration.

The group will consist of representatives from the Departments of the Treasury, Justice, Health & Human Services, the Office of Management & Budget, the Council of Economic Advisers, the Office of Science & Technology Policy, and the Office of Policy Development. The representative from the Department of Health & Human Services will serve as working group chairman.

A BILL

To protect the supply of childhood vaccines, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress Assembled,

SHORT TITLE

Section 1. This Act may be cited as the "Childhood Vaccine Supply Protection Act".

CONGRESSIONAL FINDINGS

Sec. 2. Congress finds the following:

(1) Communicable diseases are not restricted by State or national boundaries, and affect interstate and foreign commerce.

(2) Vaccinations against communicable diseases, especially vaccinations for children, have proved to be highly effective in preventing those diseases.

(3) The Federal Government has long promoted childhood vaccinations against communicable diseases, and has encouraged States to require vaccinations of children before they enter school. Most States now require vaccinations of children before they enter school.

(4) The communicable childhood diseases against which vaccinations are most needed are diphtheria, pertussis, tetanus, poliomyelitis, measles, mumps, and rubella.

(5) Vaccinations provide health protection for millions of individuals and the public as a whole, but a small number of individuals suffer serious unavoidable side effects. These side effects have led to large damage claims against vaccine manufacturers, including claims for punitive damages and non-economic loss.

(6) The unpredictability and size of claims for punitive damages and non-economic loss have made serious insurers unwilling to provide adequate coverage to vaccine manufacturers for vaccine related claims. Without this coverage, the supply of needed vaccines is threatened because vaccine manufacturers are unwilling to bear the financial risks involved in continuing to produce and distribute the vaccines.

(7) The elimination of punitive damages and a uniform national limitation on damages for non-economic loss is necessary to assure the continued availability of needed childhood vaccines.

(8) Punitive damages and unlimited damages for non-economic loss are not needed to provide equitable compensation to individuals who have suffered from vaccine side effects.

LIMITATION ON DAMAGES FOR INJURIES DUE TO CERTAIN VACCINES

Sec. 3. Part B. of title III of the Public Health Service Act is amended by inserting after section 311 the following:

"LIMITATION ON DAMAGES FOR INJURIES DUE TO CERTAIN VACCINES

Sec. 312. (a) The provisions of this section apply to all actions or claims (including wrongful death actions) filed in States or Federal court, or in connection with or before any State or Federal administrative body, proceeding or tribunal, for damages relating to the administration on or after the effective date of this section of a vaccine, and shall preempt and supersede any State law inconsistent with such provisions.

"(b) For the purposes of this section —

"(1) 'Vaccine' means any vaccine or toxoid licensed (or approved for investigational use) by the Secretary for the purpose of providing immunization against diptheria, pertussis, tetantus, poliomyelitis, measles, mumps, rubella, or any combination of the foregoing maladies.

"(2) 'Economic loss' means past and future:

(A) expenses of health and custodial care,
(B) expenses of rehabilitation,
(C) loss of earning,
(D) loss of homemaker services, and
(E) burial expenses.

"(3) 'Punitive damages' means all damages (including exemplary damages) other than damages intended to compensate for an injury.

"(4) 'Administration of a vaccine' means the administration of a vaccine or of a series of vaccines against at least one disease in common.

"(c) No punitive damages shall be awarded in any action or claim for damages relating to the administration of a vaccine.

"(d) No damages, other than damages for economic loss, shall be awarded in excess of $100,000 in any section or claim for damages relating to the administration of a vaccine. For purposes of this limitation, 'any action or claim for damages' includes all actions or claims (including multiple actions or claims) for damages, and covers all plaintiffs and all defendants in such actions or claims, which relate directly or indirectly to the administration of a vaccine to the same person."

EFFECTIVE DATE

Sec. 4. This Act shall become effective upon enactment.

Appendix C

PERTUSSIS VACCINE
(Pharmaceutical Manufacturers Association)

Drake Hotel, Chicago, Illinois

March 5, 1964

PRESENT

Dr. J. T. Anderson -- Pitman-Moore -- Physician
Dr. E. Sanders -- Parke, Davis -- Physician
Dr. M. Z. Sively, Jr. -- Wyeth -- Physician
Dr. A. F. Bolyn -- Nat'l Drug Co.
Dr. A. H. Brueckner -- Pitman-Moore
Dr. H. A. Dettwiler -- Lilly
Dr. H. B. Devlin -- Parke, Davis
Dr. J. Ichter -- Merck, Sharp & Dohme -- Physician
Dr. P. B. Koehler -- Nat'l Drug Co. -- Physician
Dr. C. Newman -- Merck, Sharp & Dohme
Dr. F. E. Peck, Jr. -- Lilly -- Physician
Dr. H. D. Piersma -- Lederle
Dr. R. E. Rowand -- Lederle -- Physician

(Cutter and Sherman Laboratories did not respond to the invitation to attend.)

SUMMARY OF MEETING

It has been long felt by those companies preparing pertussis vaccines that the mouse toxicity test bears no relationship to the clinical reactivity of a particular lot of vaccine. At the Pertussis Symposium held at the N.I.H. on October 21, 22, and 23, 1963, it was concluded that the toxicity testing should be re-evaluated and that possibly a cooperative effort in this behalf could be instituted between clinicians and laboratory personnel, as well as between the regulatory agency (D.B.S.) and pharmaceutical industry.

As a result of this meeting last week, the attending members agreed to draw up a protocol for studying the pyrogenicity of various lots of pertussis vaccine after I.V. (and I.M.?) injection in rabbits. This protocol would be presented to Dr. Margaret Pittman and her group at the N.I.H. for discussion and comments. Serving on the group to formulate the protocol are Dr. Dettwiler, Dr. Peck, Dr. Devlin, Dr. Piersma, and Dr. Ichter.

It seemed clear to me that the Lilly group is the prime moving force behind this maneuver to "attack" the mouse toxicity test. Apparently, in spite of the relative low clinical reactogenicity of 'Tri-Solgen', the mouse toxicity test often intervenes with many lots of prepared vaccine and thwarts their commercial distribution and sales.

INTER-OFFICE CORRESPONDENCE

Mathematical Analysis	April 17, 1967	Appendix D
OFFICE	DATE	

TO: Clinical Pharmacology

ATT'N OF: Dr. H. Macdonald

COPY TO: Dr. J. H. Clark
Dr. M. S. Cooper

SUBJECT: Comparison of Lilly and Lederle DPT vaccines by Dr. Blattner.

REFERENCE: Statistical Job Number 2913.

Pertussis –

A double blind study to evaluate tolerance to different commercially available preparations containing diptheria, tetanus toxoids and pertussis vaccine was carried out on 339 infant patients, by Dr. Russell J. Blattner.

Response to different symptoms for each patient was recorded as "Reaction" or "No Reaction".

When comparing Lilly product with Lederle the patients were classified according to the sex. Each sex, for each symptom was further detailed with respect to the first, second, third immunization or a booster and the (chi-square$_1$) were computed for 2 x 2 table which looked as follows:

Male

Pain (1st immunization)

	Reaction	No Reaction
Lederle	a	b
Lilly	c	d

Pooling the four different injection summary χ^2_1 were computed and are summarized in table I.

On the record of one patient it was not specified if he received immunizations or booster injection and so he was eliminated from the analysis.

In case of male, for pain, irritability and temperature, Lederle injections had significantly higher rate of reaction where as in case of females, for swelling and temperature, Lederle injection had significantly higher percent of reaction, as is shown with significant χ^2 in table I.

K. I. Shaikh

K. I. Shaikh

KIS:mlv

Appendix E

Pearl River January 10, 1972

Texas

Mr. W. R. Nudds DM

Tri-Immunol
Product No. 1948-33

Your recent travelers letter addressed to Sales Training concerning Tri-Immunol has been directed to this office for answering. We are sorry to hear that patients of two of your accounts have seemingly experienced excessive local and febrile reactions when administered this vaccine.

According to our Medical Advisory staff, immunologically some children are able to develop a rather good antibody response to the first one or two injections of Tri-Immunol; subsequent doses can then elicit what seems to be a hyperimmune phenomenon, characterized by local swelling and fever. Further, individuals may become sensitive to any of the three antigens in Tri-Immunol. Multiple antigens have distinct advantages; however, since in certain individuals the separate components may cause a reaction, a combination of components will probably increase the average of the over-all reaction rate.

In reference to the "bead method" of production, this actually refers to Influenza Virus Vaccine and not Tri-Immunol. Lederle and Lilly product Influenza Vaccine by the same process.

In the case of Tri-Immunol, the Diptheria and Tetanus components are processed similarly by both manufacturers. However, we are aware that Lilly has developed a method whereby a none cellular pertussis vaccine is obtained by fractionalization of the pertussis component. Although this part of the procedure is different both our Medical Advisory and Quality Controls staffs state that there is no reason to suspect that our Tri-Immunol is any more reactive than Lilly's.

I trust this information will be of some assistance.

Lloyd S. Carr
Product Service Manager

RJG:lw

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Appendix F

NEW PERTUSSIS VACCINES

LABORATORY AND CLINICAL EVALUATION

VOLUME II

9 a.m.

Friday, February 12, 1982

Wilson Hall
National Institutes of Health
Bethesda, Maryland

Baker, Hames & Burkes Reporting Inc
202 347-8500

cell vaccines -- I think this is the background to much of the discussion just now and, although I don't think we can open up the subject here, I would like to see some recommendations made as to the importance of investigations into basic metabolism of B. pertussis.

DR. OSBORN: Thank you. I appreciate that comment because it really should have been one of the first points that we emphasized. John, do you want to respond to that?

DR. ROBBINS: I would just suggest that one reasonable approach for the U.S. manufacturers, if they want to make this cheaply and be competitive, is either to figure out how to make it more from pertussis or get the genes out and put it into a bacterium that you can use. I mean this requires up to date science.

DR. STAINER: As a producer, I think we are starting to talk about defining something, you know, in a very nice way. But I think we also have to be very realistic. And I know that you should't bring money into an argument among scientists but I think we have to.

What we are really faced with I think now is going from a vaccine which costs literally cents to produce to one which I believe is going to cost dollars to produce. In other words, we are moving into more the viral vaccine type of costing. And I wonder whether the major users of the vaccines, which are chiefly the developing nations, where most of the vaccine is going to be used, I wonder are they prepared to pay the cost? I think it is all very well for the Canadians and for the U.S. and for Europe, they can afford it. But are we going to put ourselves in a position where we are going to have two vaccines, one for the wealthy and one for the rest? Because I don't think any of us want that. We want one vaccine. But I think we do have to be very realistic in terms of how much this is going to cost. And I would agree with what Dr. Cameron said, that, sure, you can produce a much less toxic product in very low yields, and anyone who has worked on pertussis knows this, you can get a little bit out -- maybe ten percent which is active -- and you throw the rest away.

Now, yesterday Dr. Sato said from 100 liters you get 20 liters. Now, at the moment from 100 liters of product I can get approximately 200 liters. Now, what you are saying to me as a producer is, you must increase your production another fourfold or fivefold. Now, with the enormous amount of vaccine that is required this is going to pose certain practical problems to many producers.

So I think we have to be realistic about this. I would like to think that what we are going to do is, we are going to have to take people along with us to make them realize that the vaccine can no longer be as cheap as it

Evaluation of the Pertussis Components of Diphtheria-Tetanus-Pertussis Vaccine

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ABSTRACT. The adjuvant and antigen components of the pertussis fraction of diphtheria-tetanus-pertussis (DTP) vaccine were evaluated. Four preparations of DTP vaccine composed of either whole cell (Wc) or extracted (E) pertussis antigen combined with either an aluminum phosphate (Ph) or alum (Al) adjuvant were compared. Local reactions were similar in all four vaccines after the first two immunizations but were significantly increased in incidence and severity following the third immunization with vaccine WcPh. This appeared to be due to the Ph adjuvant rather than the antigen component. Febrile reactions were experienced more often ($P = .0009$) and with higher temperatures ($P = .0001$) with the WcPh vaccine following the first immunization. This appeared to be due to the Wc component. Comparing the pooled Wc groups with the pooled E groups revealed a greater febrile response in the Wc group after both the first ($P = .0008$) and the second ($P = .03$) immunization. Local reactions appear temporally and etiologically to be distinct from febrile reactions. The pooled Wc antigen group produced a higher geometric mean titer than the pooled E antigen group ($P = .05$). Serologic responses, with respect to geometric mean titer, were not significantly different among the individual vaccines. This study suggests that the combination of whole cell and aluminum phosphate, which is currently in use in the United States, is probably not the optimal formulation for pertussis vaccine. *Pediatrics* 1983;71:200-205; *pertussis, vaccine, immunization.*

The vaccines against pertussis now used in the United States all contain whole pertussis organisms. It is recognized that the pertussis organism contains a variety of toxins that are believed to contribute to its reactogenicity.[1-3] Some of these, eg, lipopolysaccharide endotoxin, could be removed without affecting the ability of the vaccine to confer protection against infection.[1,5,6] Ideally the preferred vaccine would consist only of antigens relevant to protection without producing reactions in vaccinees. It has been suggested that, in the absence of such an ideal vaccine, an extracted preparation might be preferable to the whole cell vaccine now used.[4,7]

Pertussis vaccine has two major components: the adjuvant and the antigen. A double-blind study was designed to determine the combination of these components that would result in the least reactogenicity and yet produce an acceptable immune response. Preparations containing either whole cell vaccine or a fluid extract antigen were combined with either an alum or aluminum phosphate adjuvant. Thus four combinations were compared. All contained identical tetanus and diphtheria toxoids as presently utilized in routine childhood immunizations.

METHODS

Children attending a comprehensive care program in a county hospital were recruited. They were of low socioeconomic status, and approximately 75% were Hispanic. Informed consent was obtained from one parent of each child who participated in the study. Those with low birth weight, neurologic or cardiovascular diseases, failure to thrive, or a family history of seizures were excluded from the study.

A total of 263 doses of diptheria-tetanus-pertussis (DTP) vaccine were administered to 105 children; 75 completed the series of three doses. Children received their first dose of vaccine between 2 and 3
3 months of age. Those who failed to appear for reimmunization after an interval of more than 3
3 months were dropped from the study. Vaccines were supplied in 0.5-mL tube containers, the three
3 doses required for each patient to complete the

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series were packaged as a group. Injections were administered intramuscularly in the midlateral thigh muscle by one individual in a consistent manner. Precautions were taken to assure that injection did not take place intracutaneously or subcutaneously. The vaccine provided by the manufacturer was coded so that neither the investigators nor the parents of the vaccinees were aware of the composition of the material administered. Vaccine was stored in a refrigerator where the temperature, measured daily, was found to vary between 2° and 4°C.

The four vaccine combinations tested were: extracted antigen with aluminum phosphate adjuvant (EPh); extracted antigen with alum adjuvant (EAl); whole cell antigen with alum adjuvant (WcAl); whole cell antigen with aluminum phosphate adjuvant (WcPh). The pertussis antigen content of the two extracted vaccines was exactly the same (8 to 11 U/mL). The antigen content of the whole cell vaccines was 17 U/mL for WcPh and 19 to 23 U/mL for the WcAl. This range is within the expected range of lot variation.[8] Because of the method of preparation of these vaccines, the antigenic content could not be predicted beforehand. The aluminum, and diphtheria and tetanus toxoid content of all four vaccines were essentially identical. Therefore, it was assumed that any differences between vaccines would be attributable to the pertussis component. Assignment to one of these four groups was accomplished by a randomization table based on the enrollee number.

Parents were instructed in taking temperatures, and they were asked to record temperature between 6 and 12 hours after vaccination and the following morning. Acetaminophen drops were provided with no particular indication for usage except for "fever or discomfort." A card was provided on which parent would check (1) if the injection site was red, warm, tender, discolored, or otherwise abnormal; (2) if there was any unusual crying or screaming; (3) if the baby received any medication, and (4) other comments. Parents were asked to return the following day, at which time the card was reviewed, their child was examined by the pediatric nurse practitioner and a pediatrician, and a rectal temperature was taken.

The reactogenicity of the four preparations was assessed by evaluating systemic and local responses following each immunization. The highest temperature recorded by the parent or the clinic was used for analysis. For each vaccine group, both the percentage of patients with "high" temperatures, ie, 38.3°C (101°F) or greater, and the mean maximum temperatures were compared.

Comparisons were made of both "severe reactions," ie, any reaction of erythema or induration 10 mm or greater, and the presence of any recorded local reaction. Local reactions were evaluated at the clinic visit 24 hours after immunization at which time local erythema or induration was measured and parental records were reviewed. In no instance did a parent comment that more than a mild reaction was present without the finding being substantiated at the 24-hour follow-up visit.

Sera were obtained from 42 patients prior to the first immunization and 2 months after administration of the third dose of vaccine. Sera, which were sent to the manufacturer for antibody determination, were coded so that the testers were unaware of which vaccine the serum donor had received. Pertussis antibody was evaluated utilizing the microagglutination technique developed by Manclark.[9] Diphtheria antitoxin response was assayed utilizing a cell culture technique.[10,11] The indirect hemagglutination technique utilized by the Centers for Disease Control was employed to assay tetanus antitoxin. Standard reference antigen and antiserum were provided by the Bureau of Biologics of the Food and Drug Administration.

DATA ANALYSIS

The Statistical Package for Social Sciences[12] was used to provide the cross-tabulations of the outcome variables by dose for individual vaccine and for antigen-adjuvant groupings. Statistically significant differences were determined for the categorical variables both by χ^2 contingency test of the four groups and by preplanned comparisons between the antigen groups and between the adjuvant groups using a Z test of the differences between two sample proportions. When testing for differences, the two-tailed P value is reported. When making statements that one sample proportion is greater, a one-tailed P value is used. Measurement data such as highest temperature were compared for the four groups using one-way analysis of variance. The preplanned antigen or adjuvant group comparisons were made using the t test of the difference between the sample means.

For serologic data, the means and standard deviations of the logarithms were used to determine statistical significance. The reported geometric mean titer for each antigen-adjuvant group is a result of taking the antilog of the computed mean of the logarithms.

It should be noted that sample sizes of the samples for the third dose are small and this may lead to a type II statistical error, ie, where no significant difference is reported and larger sampling may reveal differences. This is particularly true when individual vaccine groups are compared. However, we are 95% confident using $P = .05$ that if we report a statistical difference, that the difference would in fact exist in a larger study of the sample population.

RESULTS

Local Reactions

Local reactions were examined with respect to the proportion of children experiencing any local changes or "severe" reactions (erythema or induration ≥10 mm). There were no differences among the four vaccine groups following the first two immunizations (Table 1). Following the third dose, however, both the total number of local reactions ($P = .05$) and the number of "severe" reactions ($P = .05$) were more frequent in the children receiving WcPh (Table 2).

Groups were pooled in order to compare reactions following whole cell antigen (WcPh and WcAl) and extracted antigen (EPh and EAl) and following alum (WcAl and EAl) and aluminum phosphate (WcPh and WcAl) adjuvants. No difference in local reactogenicity was found following the first two immunizations. Following the third immunization, however, total reactions (Table 1) occurred more frequently with the vaccines containing aluminum phosphate ($P = .02$); reactions to vaccines containing whole cell and extracted antigens appeared to be similar.

Febrile Reactions

Febrile reactions were compared with respect to the proportion of vaccinees experiencing "high" reactions, ie, ≥38.3°C (101°F) and for the mean maximum temperature recorded for each group. Following the first dose of vaccine, recipients of WcPh had a significantly increased ($P = .0009$) mean temperature (Table 3) and a greater proportion of individuals with a temperature of 38.3°C (101°F) or greater ($P = .001$) than those who received the other vaccine preparations (Table 4). Acetaminophen usage was increased ($P = .03$) only after the first dose of WcPh. Following subsequent doses, an increasing percentage of patients receiving the other three vaccines had increases in febrile reactions. Thus, temperatures were not significantly different following the second or third dose (Tables 3 and 4).

Pooling of the vaccine groups to compare antigens and to compare adjuvants revealed a greater febrile response to the aluminum phosphate adjuvant following the first immunization. A higher incidence of a temperature ≥38.3°C (101°F) ($P = .03$) was observed. This increase could have been due to the contribution of the WcPh group, which had a significantly higher rate of febrile reactions following the first dose (Tables 3 and 4). These reactions may have been attributable in large part to the whole cell component. Whole cell antigen recipients had the highest mean temperature following the first ($P = .0008$) and the second immunization ($P = .03$) and the highest percentage of patients with temperatures of 38.3°C (101°F) or greater after both the first ($P = .007$) and the second ($P = .03$) immunization (Tables 3 and 4).

Notable Reactions

Reactions following four of the 263 doses warrant discussion. One child who received EAl and another who received WcAl had temperatures of 40.0°C (104°F) lasting less than 48 hours following their

TABLE 1. Patients with Local Reactions (%) to Vaccine*

Dose	Individual Vaccine					Pooled Antigen Groups			Pooled Adjuvant Groups		
	EPh	EAl	WcAl	WcPh	*P*	E	Wc	*P*	Ph	Al	*P*
1 (n = 103)	41	44	38	41	*.90*	85	79	*.96*	82	82	*.80*
2 (n = 85)	21	33	35	47	*.30*	54	82	*.10*	68	68	*.90*
3 (n = 65)	44	30	15	47	*.05*	74	62	*.80*	91	45	*.02*

* Abbreviations used are E, extracted pertussis antigen, Wc, whole cell pertussis antigen, Ph, aluminum phosphate adjuvant, Al, alum adjuvant.

TABLE 2. Severe Local Reactions to Vaccine (%)*

Dose	Individual Vaccine					Pooled Antigen Groups			Pooled Adjuvant Groups		
	EPh	EAl	WcAl	WcPh	*P*	E	Wc	*P*	Ph	Al	*P*
1 (n = 103)	7.7	0	3.8	4.2	*.60*	.08	.06	*.80*	.12	.02	*.70*
2 (n = 85)	4.3	0	4.8	10.0	*.50*	2.30	7.30	*.50*	7.00	2.40	*.60*
3 (n = 65)	0	0	0	12.5	*.05*	0	5.70	*.40*	5.30	0	*.40*

* Severe is defined as >10 mm erythema or induration. Abbreviations are defined in Table 1 footnote.

TABLE 3. Mean Temperature of Children Receiving Vaccine*

Dose	Individual Vaccines					Pooled Antigen Group			Pooled Adjuvant Group		
	EPh	EAl	WcAl	WcPh	*P*	E	Wc	*P*	Ph	Al	*P*
1 (n = 103)	99.8	99.7	100.1	100.6	*.0009*	99.8	100.3	*.0008*	100.2	99.9	*.08*
2 (n = 85)	100.0	99.9	100.4	100.4	*.1900*	100.0	100.3	*.0300*	100.2	100.19	*.90*
3 (n = 65)	100.3	100.7	101.0	100.5	*.2000*	100.5	100.8	*.2600*	100.4	100.9	*.06*

* Abbreviations are defined in Table 1 footnote.

TABLE 4. Percent of Children Experiencing Temperature ≥38.3°C (101°F) Following Administration of Vaccine*

Dose	Individual Vaccine					Pooled Antigen Groups			Pooled Adjuvant Groups		
	EPh	EAl	WcAl	WcPh	*P*	E	Wc	*P*	Ph	Al	*P*
1 (n = 103)	11.5	0.0	15.4	40.9	*.001*	5.7	27.1	*.007*	25.0	7.5	*.03*
2 (n = 85)	13.6	15.0	33.3	42.1	*.080*	14.3	37.5	*.030*	26.8	24.4	*1.00*
3 (n = 65)	22.7	29.4	52.6	33.3	*.020*	25.6	44.1	*.100*	27.0	41.7	*.28*

* Abbreviations are defined in Table 1 footnote.

third immunization. The child who received the WcAl immunization was found to have otitis media when examined the day after immunization. The other child who had experienced a temperature of 40°C (104°F) on the third immunization received a booster immunization at 18 months of age with an increase in temperature to only 37.7°C (100°F) and no other severe side effects. Two other vaccinees had episodes of irritability and "screaming" following the first immunization. In an EPh recipient these symptoms were noted to last only a few seconds and were relieved when the child was held and consoled. An EAl recipient experienced intermittent "screaming" for a period of 2 hours following the first immunization. This child was also easily consoled. These children had no further episodes following subsequent immunizations and were growing and developing normally 1 year after immunization. No child had a convulsion or shock-like episode.

Severe local and systemic responses were not observed concurrently. There were 65 incidences of either a "high" febrile response, ie, a temperature of 38.3°C (101°F) or greater or a "severe" local reaction, ie, induration or erythema of 10 mm or greater. Fifty-six children experienced a febrile episode of ≥38.3°C (101°F) whereas nine others had severe local responses.

Patient Attrition

There did not appear to be a higher "drop-out" rate among any one group. Multiple attempts were made to reschedule the 28 (nine WcPh group, seven WcAl group, eight EAl group, and four EPh group) patients who failed to return after either their first or second immunization. Only one mother stated that she wished to withdraw her child from the study (group WcPh); nine infants moved or received a vaccine elsewhere and therefore became ineligible. Nineteen patients, whom we were unable to recontact, did not return for subsequent immunizations. However, 17/19 did return for their recheck 24 hours after the first immunization. Of these, seven (41%) had a temperature of 38.3°C (101°F) or greater; three were from the WcPh group, two from the WcAl group, and two from the EPh group. This percentage is similar to the 41% occurrence of fever ≥101°F in those in the WcPh group who continued in the study (Table 4).

Serologic Response

Serologic response was examined with respect to two variables: geometric mean titer (GMT), and fourfold increases or greater. Each group, except WcPh, had one individual who failed to develop a fourfold increase in titer. There was no significant difference (*P* = .17) in GMT among the four vaccine groups (Table 5).

When groups were pooled to compare the response to the antigen components, whole cell vaccines appeared to produce a somewhat higher GMT than extracted pertussis antigen (*P* = .058). In addition, whole cell vaccine appeared to act as a superior adjuvant for the toxoid components as the GMT for diphtheria and tetanus was higher for vaccines containing whole cell antigen than for extracted antigen (*P* = .02). Alum appeared to be superior to $AlPO_4$ with respect to diphtheria and tetanus titers. All groups had adequate serologic responses for diphtheria and tetanus.

DISCUSSION

The results of this study indicate that the whole cell vaccine containing aluminum phosphate, which

TABLE 5. Serologic Response to Pertussis Antigen*

Preparation	Geometric Mean Titer	*P*
EPh (n = 11)	99	*.170*
EAl (n = 8)	152	
WcAl (n = 11)	256	
WcPh (n = 12)	181	
Whole cell (Wc)	214	*.058*
Extracted (E)	118	
Alum (Al)	205	*.180*
Aluminum phosphate (Ph)	136	

* Abbreviations are defined in Table 1 footnote.

is the most commonly used vaccine in the United States at the present time, is the most reactogenic of the four combinations tested although it did not possess the highest pertussis antigen content. The whole cell aluminum phosphate vaccine produced an increase in both severe local reactions and total local reactions of any severity following the third dose of vaccine. In addition, this vaccine produced a greater frequency of severe febrile reactions and a greater mean maximal temperature following the first immunization.

In analyzing the contribution of the specific components, aluminum phosphate adjuvant was associated with the increased local reactogenicity following the third dose and febrile reactions following the first dose. The latter, however, may have been due to its combination with the very reactogenic whole cell component. The tendency of local reactions to increase with greater exposure to antigen has been reported previously.[13-15] Whole cell antigen was associated with increased febrile reactions following the first and second doses. Thus, the local reactions tend to be related to type of adjuvant and the febrile reactions to antigen.

Our findings indicate, moreover, that vaccinees tended to develop either severe local reactions or high temperatures. Only one vaccinee had both a temperature of more than 38.3°C (101°F) and a local reaction of erythema or induration greater than 10 mm. On the other hand, 64 children who had temperatures of 38.3°C (101°F) or greater did not have large local reactions and eight children who had local reactions of 10 mm of erythema or more did not have high temperatures. This observation suggests that vaccinees may be susceptible to a particular type of reaction and presumably to a particular component of the vaccine. The specificity of the reactions would suggest moreover that attempts to extrapolate reactogenicity data from local or febrile reactions to more severe types of reactions should not be made. A similar observation has been made concerning the lack of febrile or local reactions with episodes of persistent crying.[15]

Recently, assays have been developed to measure antibody by enzyme-linked immunosorbent assay (ELISA)[1] against the fimbriated hemagglutinin and the leukocyte promoting factor. These antigens have been shown to immunize mice against challenge by live bacteria.[1] These newer assays were developed in recognition of the problem of assessing the protective efficacy of pertussis vaccine by using serum agglutinins.[16-21] Although there appears to be a rough correlation between antibody titer and protection, individuals lacking detectable agglutinins have escaped infection following household exposure.[17,22] In the current study the pertussis agglutination test demonstrated that higher titers resulted from immunization with the whole cell antigen as compared with the extracted antigen. These differences, however, might be attributable to the greater antigen content of the whole cell preparation. There was no appreciable difference between the vaccines in terms of fourfold increases in titers. One might opt for the less reactogenic extracted antigen in view of the fact that it does produce an equivalent number of seroconversions, particularly in light of the present controversy concerning the significance of the protective function of the agglutinin antibody. Others have shown[1,5,6,23] that an extracted pertussis component of the antigen is less reactogenic while being adequately immunogenic.

One of the recognized properties of pertussis is its ability to act as an adjuvant.[24] In the present study it was noted that both the whole cell and the alum components had better adjuvant effect than the extracted antigen or the aluminum phosphate adjuvants.

Although the whole cell, aluminum phosphate containing antigen is the most commonly used in the United States, it is clearly the most reactogenic in terms of common reactions. Major efforts are being made to produce a purified vaccine containing only the antigen required for protection and devoid of irrelevant toxins that are present in the vaccines currently used.[1-5] Until these vaccines are available, a sufficiently antigenic, yet less reactogenic, vaccine might be prepared from the components now available. Indeed a plea has been made recently to abandon the whole cell vaccine for one containing an extracted antigen.

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Appendix H

BIOTECHNOLOGY: VACCINE DEVELOPMENT

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

FIRST SESSION

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interleukin 2, and cellular immune reconstitution employing lymphocyte and bone marrow engraftment. In the second part, patients with lymphadenopathy would be followed prospectively. At the first sign of clinical or immunological deterioration, patients would enter either a placebo or treatment arm of the trial. Treatment would consist of a combination of alpha interferon and acyclovir.

Duration: 2 years
First year cost: $1,255,000
Total cost: $2,510,000

Immunotherapy of Adult Asthma

Asthma ranks among the leading causes of physician visits, and more than $400 million is paid each year in disability benefits for asthma, emphysema, and chronic respiratory disease. Immunotherapy for treatment of asthma is widely used in adults who are allergic to extrinsic or environmental allergens. There have been no studies using currently available monitoring and diagnostic technology to determine the effectiveness of such immunotherapy. This clinical trial would determine the efficacy in asthma management of five standardized allergenic reagents: cat, ragweed, mite, alternaria, and timothy.

Duration: 6 years
First year cost: $1,000,000
Total cost: $6,000,000

Pertussis Vaccine

The currently available pertussis vaccine is effective and well accepted in the U.S. However, undesirable and sometimes severe reactions to the vaccine have been observed. Using newer technology an acellular vaccine has been developed in Japan and is in general use there. Preliminary reports from Japan indicate that the vaccine is effective and relatively free of side effects. This trial would be conducted using a Japanese-type vaccine and would use a preparation produced in Japan and packaged in the U.S. or produced entirely in the U.S. Following evaluation of the vaccine in three NIAID vaccine evaluation units, an efficacy trial would proceed in a country with sufficient disease incidence.

Duration: 4 years
First year cost: $150,000
Total cost: $2,250,000

Monoclonal Antibodies in Kidney Transplantation

Kidney transplantation is a curative and more definitive treatment for end stage renal disease than dialysis. Current medical strategy for kidney transplants includes chemotherapy to suppress the immune system and the use of equine anti-human thymocyte globulin to interrupt rejection episodes. Both treatment modalities have attendant problems which need to be overcome. Monoclonal antibodies, specific for human T lymphocyte subsets, would be ideal therapeutic agents for both preventing and interrupting rejection episodes.

Appendix I

SELECTIVE LIST OF
MAJOR STUDIES
ON PERTUSSIS VACCINE REACTIONS

YEAR OF PUBLICATION	AUTHOR, TITLE, PUBLICATION
1933	Madsen, "Vaccination Against Whooping Cough," Journal of American Medical Association. Called attention to two deaths shortly after pertussis vaccine injection; "furthermore, some of my colleagues have told me that they have seen considerable malaise following the vaccination."
1936	Doull, Shelbley & McClelland, "Whooping Cough Immunization," American Journal of Public Health. "Three children are stated to have had convulsions within 12 hours following inoculation, and, in 1 of these, convulsions were observed by a nurse."
1938	Taylor, "Reaction Following Injection of Pertussis Vaccine," Archives of Pediatrics.
1946	Werne & Garrow, "Fatal Anaphylactic Shock: Occurrence in Identical Twins Following Second Injection of Diptheria Toxoid and Pertussis Antigen," Journal of American Medical Association.
1948	Byers & Moll, "Encephalopathies Following Prophylactic Pertussis Vaccine," Pediatrics. Fifteen case histories reported "In common with many other biological materials used parentally, an important risk of encephalopathy attends the use of prophylactic pertussis vaccine... Efforts to diminish the hazard by modification of the vaccine or new methods of administration seem indicated."
1949	Globus & Kohn, "Encephalopathy Following Pertussis Vaccine," Journal of American Medical Association. The alarming character of this reaction to a widely employed prophylactic agent prompted us to report the following two cases" (including one death).
1953	Kong, Helv. Paediat. Acta 8, 90. [Review of 107 reported cases of serious pertussis vaccine-related reactions].

1958 Berg, "Neurological Complications of Pertussis Immunization," British Medical Journal.

"It is generally agreed that the pertussis antigen in all these vaccines is responsible for the reported neurological sequellae. There are good grounds for this view."

1960 Strom, "Is Early Immunization Against Pertussis Always Justified, British Medical Journal.

If use of triple vaccination is to be continued its hazards should be appreciated and certain contraindications emphasized... The increasingly mild nature of whooping cough and the very low mortality in this disease in Sweden makes it questionable whether universal vaccination against it is justified."

1961 Hopper, "Illness After Whooping Cough Vaccination," The Medical Officer.

Study of 52 cases of illness following pertussis vaccination.

1967 Strom, "Further Experience of Reactions, Especially of a Cerebral Nature, In Conjunction With Triple Vaccination: A Study Based on Vaccinations in Sweden, 1959-1965," British Medical Journal.

"...it is emphasized that when nationwide vaccination is recommended detailed information should be required concerning postvaccinal reactions, as is done in Sweden in conjunction with triple vaccination."

1969 Hannik, "Major Reactions After DPT-Polio Vaccination in the Netherlands," International Symposium on Pertussis (1969).

Analysis of fifty reported shock or convulsion reactions to DPT-polio vaccine.

1972 Wade, "Division of Biologic Standards: The Boat That Never Rocked," Science.

Refers to "the sometimes weak-kneed stance the DBS has taken in persuading manufacturers to improve the quality of their vaccines" and cites "pertussis vaccine" as an example of DBS' inadequate efforts to improve existing vaccines. "...there are dangers that problems will be underemphasized in any system that discourages the fullest possible discussion, as some believe DBS does."

1974 Kulenkampff, Schwartzman, & Wilton, "Neurological Complications of Pertussis Inoculation, Archieves of Disease in Childhood.

Analysis of 36 children hospitalized with neurologic illness occurring up to 14 days after DPT inoculation. "We do not think ...that the majority of cases we report here represent a chance association because of the clustering of illness in the 7 days after inoculation and particularly in the first 24 hours." Recommends strengthened reporting system for vaccine reactions.

1978 Grady, "Pertussis Vaccine: Reasonable Doubt?" New England Journal of Medicine.

"The inadequacies of voluntary reporting [of serious vaccine reactions] are acknowledged ...Ironically relative equanimity about the use of pertussis-containing vaccines in the United States can generate complacency about the need to improve the product."

1979 Final Report, Panel on Review of Bacterial Vaccines and Bacterial Toxoids, Food and Drug Administration.

"Some standards of purity ... for well established vaccines are based on old fashioned methods which should be updated by more sophisticated techniques made possible by advancing scientific knowledge ...Efficacy and safety should be assessed and defined in terms of more modern standards of quantitative immunobiologic testing, chemical purification, and clinical evaluation. The motivation and impetus to accomplish this is unlikely to come spontaneously from pharmaceutical manufacturers unless review of vaccine licensure is conducted periodically." ...

"[Pertussis] vaccine is highly reactive and very justifiably attempts to reduce its reactivity by purification are virtually thwarted by the dependence on [existing means of assessing vaccine efficacy]."

1980 Mortimer, "Pertussis Immunization: Problems, Perspectives, Prospects," Hospital Practice.

Notes, among other things --

- "the fact that pertussis vaccine reactivity is notoriously under-reported and poorly monitored";
- "It is clear ...that efforts should be made to 'clean up' DTP."
- "As for existing vaccine potency and toxicity tests, there is general agreement that improvements need to be made."

Dissatisfied Parents Together (DPT) 128 Branch Road, Vienna, VA 22180 (703) 938-DPT3

July 19, 1985

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Senator Orrin Hatch, Chairman
Senate Labor and Human
    Resources Committee
Washington, DC 20510

Dear Senator Hatch:

With your permission, we would like this letter to be included in the printed record of the July 18, 1985 hearing entitled "Childhood Immunization: Problems and Options" immediately following completion of the parents' panel's presentation.

In her testimony, Mrs. Marge Grant indicated her concern that the vaccine injury table in section 2105(a)(1) of S. 827 is too restrictive. Her testimony suggests that, because of this, a number of vaccine-injured children would not be eligible for compensation under S. 827. Mrs. Grant uses her son's case as an illustration.

We believe that Mrs. Grant has misunderstood the intent and effect of S. 827, and present this letter to explain the basis of our belief that cases such as Scott's would be covered and entitled to compensation under S. 827.

It is important to note that S. 827 provides two alternative bases on which a claimant can gain compensation:

1. Section 2105 (a)(1) provides a set of circumstances which, if satisfied, create a presumption that the injury was caused by the vaccine;

2. Section 2105 (a)(2) provides that a claimant may, independent of any presumption, present evidence to demonstrate a causal connection between the injury and the vaccine.

It is also important to understand what must be shown to create the presumption. An application of these provisions to Mrs. Grant's situation will further explain their meaning.

First, the vaccine injury table on page 16 of the bill (Section 2105 (a)(1)) states that for the presumption of vaccine causation to apply, the "first symptom or manifestation of onset" of the covered injury must occur within the stated time period. This does not mean that an encephalopathy or residual seizure disorder must be entirely manifest within 7 days after the pertussis shot is given. Rather, it means that the first neurological symptom or sign of what ultimately is determinted to be an encephalopathy must occur within 7 days for the presumption to apply.

Thus, in Scott's case, where the first neurological symptoms of his encephalopathic reaction occurred "the morning after his third shot," but the infantile spasm manifestations of that encepalopathy did not appear until after the seventh day, his situation would in our view still fall within the vaccine-injury table.

In this connection, note the broad definition of "encephalopathy" in section 2164(9) of the bill, and the findings of the National Childhood Encepalopathy Study which strongly suggest that infantile spasms appearing more than a week or two after the pertussis shot may represent an encephalopathic reaction to the shot.

The important point for the purpose of the proper interpretation and implementation of the vaccine injury table in section 2105(a)(1) is not when the infantile spasms occur, or even when the encephalopathy (of which they are an overt sign) occurs; the important point is when "the first symptom of onset" of the encephalopathy occurs in relation to the shot.

In support of this reading of the bill, see also section 2105(b)(3), (4), and (5) and 2105 (c)(7). This was a point which was discussed specifically between Dissatisfied Parents Together and the American Academy of Pediatrics in the talks which led to the development of, and our agreement to support, S. 827.

Second, even if our reading of section 2105(a)(1) of the bill were incorrect (which we believe it is not), a separate and independent ground upon which vaccine-injured children, such as Scott Grant, could be compensated is set forth in section 2105(a)(2) of S. 827. That provision makes clear that any vaccine-caused injury must be compensated (whether or not the vaccine injury table applies), if the requirements of sections 2103 and 2104 of the bill are met. Thus, if a vaccine-caused injury were of a nature not specified in the table, it would still be compensable if credible evidence submitted by the petitioner shows a causal connection between the vaccine and the injury.

Similarly, the time interval between the shot and the onset of the symptoms would be relevant to the issue of causation, but would not be dispositive of the issue. Thus section 2105(a)(2) of the bill leaves wide room for vaccine-injured children to be compensated, whether or not their circumstances meet the presumptive causation conditions of the vaccine-injury table of section 2105(a)(1) of the bill.

We appreciate the opportunity to clarify the record on this point.

Sincerely,

Jeffrey H. Schwartz

Jeffrey H. Schwartz, President
Dissatisfied Parents Together (DPT)

JHS:kks

Dissatisfied Parents Together (DPT) 128 Branch Road, Vienna, VA 22180 (703) 938-DPT3

August 26, 1985

Honorable Orrin Hatch
Chairman, Labor & Human Resources Committee
United States Senate
Washington, D.C. 20510

Dear Senator Hatch:

Enclosed in response to your letter of July 24, 1985, are the answers to the questions which were submitted to Dissatisifed Parents Together (DPT) in writing by members of the Senate Labor and Human Resources Committee as part of the July 18 hearing on "Childhood Immunization: Problems and Options." We respectfully request that these answers be made part of the printed hearing record.

> Question 1: Why do you think a compensation system is necessary, when we have recourse available through the courts? Could you describe briefly specific problems that you have had with the court system that convince you that a government compensation system is necessary?

Answer 1: Dissatisfied Parents Together (DPT) favors establishment of a compensation system, but only so long as it remains an option available at the election of parents (or injured adults) and only so long as it is designed not to undercut incentives provided by the tort system for greater care in vaccine research, production, testing, labeling, warning, etc. The specific reasons that we believe many parents would opt for a compensation system (like that provided in S. 827) instead of the tort system, if given the choice, include the following:

(A) The difficulty of suing the vaccine manufacturer in cases in which the doctor or clinic has failed to record (or otherwise identify) the particular manufacturer or vaccine administered;

(B) The delay and expense involved in the tort system;

(C) The adversarial nature of the tort system, and the stress which it imposes on families already under great stress;

(D) The uncertainty of achieving an adequate settlement or verdict to provide funds to care for a seriously injured child and to compensate for lost income, pain and suffering, etc., coupled with the fact that attorneys' fees and expenses may reduce the amount of any tort settlement or verdict by 25-50%; and

(E) The existence in a few states of inappropriate statutes of limitations or repose (or malpractice award caps) which unduly restrict tort awards for the care of vaccine-injured children.

> Question 2: All of the legislative proposals that have emerged thus far have included "no fault" systems. You seem to support this concept, although your testimony makes clear that you do not believe this is truly a no-fault situation; e. g., you call for a congressional investigation of fault in the industry, pursuant to negligence in developing and marketing safer vaccines. Could you explain this apparent inconsistency?

Answer 2: There is no inconsistency, apparent or otherwise. As a matter of fact, we believe that in most, if not all, cases of pertussis-related vaccine injury, manufacturers (and sometimes physicians) have been at fault. As a matter of policy, we believe children injured by any mandated childhood vaccine should have the right to full compensation without the requirement that they prove fault. There is nothing inconsistent in this.

Dissatisfied Parents Together (DPT) believes that the record is clear that most, if not all, cases of pertussis vaccine-related injuries in the last 20-25 years were fault-induced and preventable, had responsible action been taken by manufacturers, physicians, and federal vaccine regulators. A portion of the proof to support this assertion may be found in the following sources:

(A) Coulter and Fisher, DPT: A Shot in the Dark, Harcourt, Brace, Javonovich, New York, 1985;

(B) Advocates for a Safe Vaccine, DPT Vaccine: Interim Report (unpublished, but supplied to the Committee, 1985);

(C) Collins and Hanchette, The Vaccine Machine, Gannett News Service Special Report (December 1984);

(D) Tompkins, DPT, Reprint from The Fresno Bee (1984);

(E) "20/20", ABC News, segments on DPT (February 5, 1985);

(F) Tinnerholm v. Parke-Davis & Co., 411 F. 2d 48 (2d Cir. 1969); Parke-Davis & Co. v. Stromsodt, 411 F. 2d 1390 (8th Cir. 1969); Toner v. Lederle, -- F. Supp. -- (D. Ida. 1984); Wilson v. U.S., --F. Supp. -- (N.D. Ga. 1983); and the increasing number of cases settled by pertussis vaccine makers on the condition that critical documents concerning manufacturer fault be sealed and kept secret.

Thus we believe there is ample evidence to show that pertussis vaccine manufacturers have been at fault for the last 20-25 years and that this fault resulted in injuries and deaths that could have been avoided. Nonetheless, we believe parents of vaccine-damaged children should have the right to receive compensation without having to prove the existence of fault in an adversarial proceeding. Childhood vaccines are the only products which are known to be hazardous, yet are mandated by law for the protection of public health. Because of this fact, we believe Congress has a duty to provide an adequate means for compensating those children who are injured by vaccines (regardless of whether or not any fault is proved), as well as to assure that the safest possible vaccines are available and otherwise minimize the risks of vaccine-induced injuries and deaths.

Finally, we note that S. 827 would apply to injuries caused by mandated childhood vaccines other than pertussis. As to these vaccines, we offer no opinion whether or not fault by manufacturers can be proved in all cases. We do note, however, Griffin v. U.S., 500 F.2d 1059 (3d Cir. 1974), in which a defective lot of polio vaccine was found to have caused a woman to become a quadriplegic.

Under the circumstances, we see no inconsistency, apparent or real, in arguing that in many cases the fault of manufacturers and doctors causes the vaccine injury, but that a non-adversarial means of compensation (not requiring proof of fault) should be available, if parents prefer to use it rather than the tort system.

> Question 3: Is it your view that if a compensation system were established, all cases of vaccine-related injury, as defined by the table of compensable events, should be covered, no matter how long ago they occurred? Is such an indefinitely retroactive system not likely to be unrealistic because of its cost?

Answer 3: Yes, Dissatisifed Parents Together (DPT) favors establishment of a compensation system to redress vaccine-induced injuries regardless of how long ago they occurred. Equitable treatment of these children requires no less. Moreover, the question wrongly assumes that there are no costs associated with the current system. If a compensation system is not made an available option to those who have already sued (or plan to do so) for past injuries, the costs of these injuries will be paid for through the tort system, with its attendant high transaction costs.

In addition, some of the costs for vaccine injuries are currently being paid for by taxpayers, through such programs as Social Security disability and SSI, the Education for All Handicapped Children Act, Medicaid and public institutionalization programs. Under the current system, vaccine-injured children compete with other needy families for increasingly scarce public aid. To the extent that adequate training and rehabilitation are not provided to these children, the taxpayer will again ultimately pay, in higher unemployment and welfare costs and reduced productivity as these children become adults.

Of course, not all the costs of vaccine injuries are paid for by either the tort system or various public aid programs. Some are borne by the families of these children or by the children themselves, in the form of lost opportunities for realization of their potential. In addition, because the injured parties are children, their family's ability to care for them may, realistically, be limited to the parents' lifetimes. It is the nightmare of the parent of every handicapped child to die before the child, and to anticipate what will happen when the child must rely on the public sector for sustenance. The attractiveness of both the tort recovery and a compensation system is that it provides for the needs of the child for the life of the child, beyond the lives of the parents.

In our view, a more "realistic", cost-effective and equitable approach to the current situation would be to create an attractive (to parents) yet fair compensation option and encourage (but not force) parents to elect the option, regardless of when the injuries occurred. To fail to offer such an option to those injured prior to the date of enactment will result in inequity, more lawsuits, more costs, and, for the manufacturers, more (not less) uncertainty.

Finally, if one primary goal is a more "realistic" approach to keeping costs down, then Congress should make its highest priority safer vaccines and the prevention of vaccine-caused injuries.

> Question 4: According to your testimony, your goal is to make today's situation different, and better for tomorrow's children. What would be your view of indemnification by the government of mandatory immunization programs, starting now and retroactive for perhaps two to five years?

Answer 4: Dissatisfied Parents Together (DPT) would oppose such a proposal. It would remove the incentive for development of safer vaccines, and for greater care in the manufacture, quality control, testing, labeling, warning, field surveillance, recall and administration of vaccines. It could, therefore, lead to more vaccine-damaged children, not less. In addition, it could open federal coffers to unlimited expense. It would be a duplicate of the Swine Flu fiasco. And there has been no compelling showing that any such action is even needed.

We do support the provisions of S. 827 which authorize HHS to provide insurance pooling, reinsurance, or direct insurance, if necessary. But these authorities are discretionary, not mandatory, and may only be exercised upon proper showing of need and imposition of conditions to assure due care by vaccine manufacturers in all aspects of their responsibilities to consumers.

> Question 5: In the context of proposals before the Committee on Environment and Public Works, representatives of the chemical and other industries have repeatedly made the statement that the risk of injury, without regard to its source, is simply a risk of living in a modern technological society. People are going to become sick, and it is unfair to compensate one set of victims while doing nothing for others. How would you respond to this?

Answer 5: I personally would favor a system of universal catastrophic injury health insurance. Dissatisfied Parents Together (DPT) has no position, however, on this point.

We would point out, however, that contrary to the assumption that is discussed in the question, many of these vaccine-induced injuries were not inevitable. They could have been avoided had due care been taken.

Perhaps even more importantly, in the case of mandated childhood vaccines, there is no willing "assumption of risk", since children were and are required by law in many states to receive these vaccines. Even in states with a right to a "philosophical or personal" objection, there is a question whether this right may be exercised selectively (accepting some vaccines, while rejecting others), and, in most of the states, parents receive no notice that they have any such rights.

When the states (at federal insistence to promote the federal immunization program) mandate a product which is known to be hazardous, the government has some responsibility to assure the availability of adequate means of compensation for those children (and adults) who are seriously injured by that mandated product.

Question 6: Do you trust the Department of Health and Human Services to set up a fair and impartial system for settling questions of compensation?

Answer 6: We do not, and we have the following reasons, among others, for this mistrust:

(A) The most recent HHS/Administration legislative proposal, which provided for no compensation system at all, only the elimination of punitive damages in all vaccine cases, regardless of the degree of fault, and restriction of pain and suffering and loss of consortium damages in tort suits;

(B) The grossly inadequate efforts of HHS/FDA in the past to manage the vaccine licensure system to assure the production of safe vaccines, adequate testing of vaccines, reporting of adverse reactions, etc;

(C) The institutional conflict of interest between HHS's role, as promoter of immunizations, licenser of vaccines, and advocate of health cost containment, and its new responsibility to assure adequate compensation for vaccine-damaged children;

(D) HHS' denial and undue minimization of the potential for vaccines to cause severe injuries, and its funding of, and reliance on the advice of, so-called "experts" who have, at the same time, appeared as paid witnesses for the defendant vaccine manufacturers in tort suits;

(E) HHS' exclusion of parents of vaccine-injured children from its advisory committees and policy-making work groups;

(F) HHS' continuing failure to probe seriously the allegations of wrongdoing by vaccine manufacturers, and, until recently, HHS's failure to promote research into safer vaccines or into adequate means of identifying high risk children;

(G) HHS' continuing failure to disclose the full range, frequency and severity of vaccine risks to both physicians and parents;

(H) HHS' susceptibility to political control from OMB or others in the Administration; and

(I) HHS' continuing failure (after over 10 years of "study") to give any advice to Congress or the public as to the criteria it would use, if directed to implement a vaccine-injury compensation program.

Under these circumstances, leaving the criteria or selection of "experts" for a compensation program up to the discretion of HHS (or "experts" selected by HHS) is unacceptable to Dissatisfied Parents Together (DPT). We believe no parents would opt into an HHS-designed "compensation" system. Congress must set the criteria for such a program and the politically more independent federal judiciary must be assigned ultimate responsibility for case-by-case fact finding.

> Question 7: Do you accept the industry's claim that the current vaccine is the safest that can be produced and that the manufacturers bear no real liability for any injuries which result from the vaccine, since all such injuries represent the small, but unavaoidable, risk that accompanies the vaccine?

Answer 7: As the Appendices to our July 18 testimony show (and as the references cited in Answer #1 confirm), this claim just is not true. This is the claim that we think Congress needs most to investigate. New evidence has come to light since the July 18 hearing which sheds further doubt on that claim (at least as applied to pertussis vaccine). Materials discovered in the course of the Chikasuye case warrant particular attention.

Moreover, it is difficult for Dissatisfied Parents Together (DPT) to take seriously the pertussis vaccine manufacturers' claims that they should be held harmless on the ground that they complied with federal "safety" standards. How can this argument even be made with a straight face? The pertusssis vaccine manufacturers knew (and have known since prior to 1964) that the only federal "safety" test did not measure the vaccine's propensity to cause the neurological side effects that were of concern. Yet they made little or no effort to warn the government, physicians or the public of this fact, to develop an appropriate test, or to develop a safer pertussis vaccine. We have made this argument on many occasions in the last six months. Always the pertussis vaccine manufacturers remain mute in response, except to reiterate (unexplained and unsubstantiated) their claims of "no fault" and "unavoidable injuries."

> Question 8: The implication hanging over this whole issue is that suits brought by concerned parents like yourselves have caused the current vaccine shortages and the 4000% increase in the price of PDT vaccine over the last two years. How do you react to that?

Answer 8: First, it must be made clear that the unsafe vaccines and manufacturer negligence which have caused needless injuries to children are the primary problem, not the lawsuits, which seek to redress these wrongs.

Second, the manufacturers have claimed that vaccine cost increases were attributable to the lawsuits, but they have not substantiated their claims. In fact, under questioning by Rep. Waxman, the President of Lederle admitted that less than 40% of the price increase Lederle had imposed was due to litigation costs, while the remainder was being used for expansion of production capacity and research and development. See "Vaccine Injury Compensation," House Health and the Environment Subcommittee Hearings, 12/19/84, p.301. In this connection, Lederle explained that while it was being charge only 20¢/dose by Wyeth, it was selling the same vaccine for $2.80/dose, a mark-up of more than 1400%.

Furthermore, the 1984 annual report of American Cyanamid (Lederle's parent company) stated, "In 1984, the Medical Group set sales and operating earnings records." The annual report goes on to note that one of the contributing factors to the profitability of the Medical Group was "substantially higher U.S. sales of biologicals [vaccines]." Cyanamid also advised the Securities and Exchange Commission in its 1984 10-K report:

> In the opinion of management, the ultimate liability resulting from all pending [vaccine-related] suits and claims (after taking into account the insurance coverage) will not have a material adverse effect upon the consolidated financial position of the company and subsidiaries. (P.9)

In light of these facts, we believe Congress should be investigating the unsubstantiated claims of the vaccine makers, not accepting them uncritically.

Likewise, it is clear that despite Lederle's and Connaught's claims of the unavailability of liability insurance, both have obtained insurance for 1985. To the extent that there may have been some difficulty in obtaining liability insurance, this is not uniqure to the vaccine manufacturers. The liability insurance issue is a broader one and cannot appropriately be addressed solely in this legislation. We note, however, that if the unavailability of private insurance can be substantiated in the future, S. 827 would provide authority for HHS to make the necessary arrangements to assure availiability of insurance and vaccine supply. We support this authority, but believe it should be exercised only upon use of subpoena power to prove that vaccine makers are not merely "crying wolf" -- again!

Finally, the claims of a vaccine "shortage" overlook the fact that there actually was an adequate supply. Connaught merely refused to release up to 3 million doses of vaccine that it had produced, in an attempt to stampede Congress into granting it immunity from liability for its own negligence. Once Congress made clear that it would not grant blanket immunity, Connaught obtained insurance, re-entered the market, released the 3 million doses, and the so-called "shortage" disappeared.

Question 9: What is your advice to parents who are taking their children to get DPT shots today?

Answer 9: Our group does not give medical advice. We do recommend that parents be fully informed before making this important medical decision, just as they would with any other important medical treatment. In this regard, we do provide information which parents can use to make up their own minds, depending on the specific circumstances of their child and the laws of their state. The parent information packet is available for $3 (to cover costs) from

DPT
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Question 10: What, in your opinion, is the single most important thing that we could do to improve our national childhood vaccination program?

Answer 10: No one single action will fix the problems with the current vaccine program. Congress needs to first conduct an investigation to get the truth -- the American public's confidence in the program depends on this foundation.

Next, Congress needs to make safer vaccines and a better vaccine safety program its highest priority. This includes retaining the tort system's incentives for the safest possible vaccines and the highest standards of care in their manufacture, testing, warnings, etc. If the pressure of the tort system is removed entirely or severely undercut, neither industry nor government will have the incentive to produce the safest possible vaccines. Only the tort system thus far has resulted in real oversight and investigation of the so-called "vaccine safety" program.

Third, the public must be informed and a real system for mandatory recording and reporting of severe reactions must be put into place. Without this information, the public's doubts about the claimed benefit-risk ratio of other vaccines will grow, just as it has with respect to pertussis vaccine.

Finally, an expedited, fair, non-adversarial compensation system should be made an option for injured children, if their parents elect, in lieu of the tort system.

In short, S. 827 should be passed without weakening amendments, but first Congress should conduct an open-books investigation of the vaccine makers' claims.

Reformation of the vaccine system is crucial to the prevention of needless vaccine injuries in the future, particularly when many new childhood vaccines are currently being developed by federal and private researchers for mass use. Congress needs to act to ensure that the vaccine system does not fail America's children with new vaccines, as it has with the pertussis vaccine.

> Question 11: With respect to this question of vaccine safety once more, has your group looked into current production standards, and do you have any recommendations to make with respect to changing those standards or any aspect of the production process which you think would improve the safety of vaccines?

Answer 11: Our group is in the process of reviewing these issues at present. However, there are a number of changes in general which we believe are warranted in production and testing standards and which would tend to reduce the frequency and severity of serious adverse reactions. Among the general types of changes which we believe are warranted for pertussis vaccines are the following:

(A) Repeal of the "irrelevant" mouse toxicity test and replacement with a screening test which validly measures (or correlates with) the vaccine's neurotoxic potential in human beings;

(B) Requiring a minimum 90% reduction of endotoxin from current whole cell pertussis vaccines (or applying the same endotoxin limits as the FDA imposes on influenza or meningococcal vaccines, whichever is more stringent), and requiring further toxoiding of pertussis toxin (PT);

(C) Prohibiting bioactive Lymphocytosis Promoting Factor (LPF) from exceeding a carefully set ceiling concentration level;

(D) Narrowing the range of allowable variability in the potency of pertussis vaccines to prohibit excessively potent vaccines from entering the market by --

(i) repealing the U.S. opacity standard and substituting the more stringent WHO standard, which the rest of the world meets;

(ii) reducing the allowable protective unit ceiling from 32 protective units to 12 protective units (perhaps less). [The current standard allows manufacturers to market vaccines with protective unit numbers as low as 8 and as high as 32, yet the labels of all pertussis vaccines now indicate they contain 12 units.]

(E) Requiring labeling of actual potency of, and amounts of toxins contained in, pertussis vaccines; and

(F) Requiring pyrogen testing (to assess the fever-inducing capacity of the vaccine) which is at least as stringent in effect as the pyrogen testing FDA requires for some other biologicals. No such testing is now required for pertussis vaccines.

Until measures such as these are required and enforced by the FDA and met by the manufacturers, the manufacturers' claims of compliance with government standards as a defense to negligence ring hollow. For the government to permit a 2700% variation in the potency of pertussis vaccines from lot-to-lot, as well as similarly large variation in the amount of bioactive LPF content from lot-to-lot, and up to 10,000 times more endotoxin in pertussis vaccines than in other vaccines is inexplicable and inexcusable. HHS' laxness in these respects is no excuse for similar indifference by vaccine makers, but it does explain why Dissatisfied Parents Together (DPT) believes that HHS cannot be trusted. It will apparently take more public pressure, more Congressional oversight, citizen suits, and continued availability of tort remedies before HHS and the manufacturers take their responsibilities seriously.

We appreciate the opportunity to respond to the questions of the Committee.

Sincerely,

Jeffrey H. Schwartz

Jeffrey H. Schwartz, President
Dissatisfied Parents Together (DPT)

JHS:kks

Senator HAWKINS. Thank you.

The court reporter will note the number of parents who are here. We commend you for being interested and caring enough to travel this far. Stay in touch with this Senator because I'm vitally interested in it.

We have been joined by Senator Pell who is a cosponsor of S. 827.

Do you have an opening statement or comment, Senator Pell? We welcome you.

Senator PELL. Thank you very much, Madame Chairman. I just congratulate you on your interest and willingness to chair this hearing and the three previous hearings on the Childhood Vaccination Program.

I realize the agony and the misery that the lack of a proper program and care in this regard has caused people throughout our Nation, and some of them right here in this room.

I am very glad, indeed, to have cosponsored S. 827.

Senator HAWKINS. Thank you, Senator.

Do you have any questions of Mr. Schwartz, Senator Kerry?

Senator KERRY. Mr. Schwartz, could I ask you what your occupation is?

Mr. SCHWARTZ. Yes. I'm a lawyer. I am an environmental consultant.

Senator KERRY. And at the time that you took your child in for the vaccine, what was your level of knowledge at that point about vaccine danger?

Mr. SCHWARTZ. I regarded myself generally as a reasonably educated consumer who was skeptical about all kinds of things, and so asked some hard questions. But this was in 1981, before "DTP Vaccine Roulette" appeared on television, before that subject was being widely discussed popularly. So at the time I was not aware that DTP vaccine could cause convulsions and brain damage and death.

Senator KERRY. I think we are all in agreement here—I hope we are all in agreement—that obviously one of our objectives has to be to establish standards which are going to achieve greater safety in the vaccine process itself; but obviously, until that happens, parents with really far less background and less knowledge than yourself are going to be having their children vaccinated. And in the traditional relationship of patient-doctor in this country, they will, trustingly, put themselves entirely into the process, and really, into the doctor's hands.

Therefore, I'm interested in this question of what we ought to do or think about doing with respect to information and information-flow transfer. You said you had some other thoughts on that. I would like to just pursue that idea for a moment, if we can, because it seems to me that somewhere along the line there's got to be some very special kind of transfer of knowledge concerning risk assessments. Without such transfer the suggestions of this bill, or other options available to us would become impacted on a legal basis, as well as otherwise. I wonder what your thoughts are on that—if you want to share them with us?

Mr. SCHWARTZ. I appreciate it, Senator Kerry.

There are two things to say: one is that because this information was not forthcoming from any other source, DPT itself read the medical literature, consulted with our medical advisers, and put together the parent information book that——

Senator KERRY. Let me just say something. Is this—I think I have it here. Is this the book. Is this the equivalent, or is it larger than that?

Mr. SCHWARTZ. I believe that's it. It looks like it. It's called "Pertussis and Pertussis Vaccine, Parent Information."

Senator KERRY. Correct. "Information for Parents, Part One," and then——

Mr. SCHWARTZ. Well, part 1 is an earlier version. We have now done an update that tracks changes in the recommendations, but that's the basic book. For instance, when we were on Nightline, we announced the availability of this book, for $3 to cover our costs, and parents wrote in to our office. We got 4,000 letters alone, with $3 in it, asking for this information—and not just from parents. The thing that's fascinating was, requests came from immunization clinics, from school nurses, even from physicians.

One of the letters that really affected us was from a doctor in Maine, a family practitioner, who said, "I am ashamed that my profession didn't put this information together. I am grateful to the parents for having put it together, and I use it in my office now."

We would love to go out of this business, frankly, because it's not the parents' job—ultimately, it ought not to be parents' jobs to have to inform other parents about the risks of the DPT vaccine but until the medical community takes the right kind of responsibility that includes consultation with the consumers in the development of that kind of information—until that happens, we will continue to make our book available and urge parents to send in their $3—and, with your permission, I would put in the record our address. It's 128 Branch Road, Vienna, VA 22180. And people can write in, and if they send $3 to cover costs we will send them that parent information package.

This information gives them the ability to contend with their doctor, because when their doctor says, "Oh, no, convulsion isn't related to DTP," they've got right there the citations to the relevant literature, and say, "What about this?" And the doctor says, "Oh, maybe I had better look into that."

Well, parents are going to have to contend with their doctors, not to fight against immunization programs, but some children should get the vaccine and other children shouldn't, and some should stop after they have certain reactions.

You see, we treat this all like it's a black and white issue, like everybody should get pertussis vaccine or nobody should get it. That's not right. It should be administered discreetly. It is known to contain dangerous toxins—it has its benefits but it has risks, and those need to be known.

So one answer is, until the government does its job and the medical community does its job, the parents will have to keep doing the job; and the second answer is that there, frankly, needs to be honest and open discussion about the dangers of the vaccine.

"20/20" helped do that. Some say that show was oversensationalized—maybe. I think it told the truth. Yet we know at least one drug company tried to suppress that show at the highest level. We know that every time a show has come up that tried to inform the public about the risks of the vaccine, it's been called journalistic malpractice. The government has been involved in this name calling and so have the doctors.

Now, I understand the concern that we not frighten parents needlessly. It would be tragic if, in our attempt to help future children, we dissuaded parents from getting vaccines that their children need and they die. I don't want to be part of that, and I won't be part of that.

But there is a way to get balance and the truth, and the way is, give it to the media. Let the media tell this story, encourage the media to tell the full story, and demand that they tell it—and your hearing here today will help make that happen.

Senator KERRY. Thank you. I read parts of your booklet. I think it's a really outstanding piece of work. I suppose my only fear is that it's quite a bulk of reading for each parent to try to go through, and my fear is that most people simply won't read all of the material or have access to it.

Mr. SCHWARTZ. We need to have—we are working on a shorter, more concise version, but——

Senator HAWKINS. It's a labor of love, after a fashion.

Mr. SCHWARTZ. Yes. I think that needs to happen.

Senator KERRY. I congratulate you on your efforts, and really thank you for what you are doing. I think it's terrific.

Thank you, Madame Chairman.

Senator HAWKINS. Thank you, Senator.

I love working with Jeff, and he's doing a wonderful job.

Of course, the answer is safe vaccine, which we are working on. We have it down to—protocols are now being conducted in Sweden, children 18 months and less; and, hopefully, in a year, maybe two, we will have the safe vaccine.

Mr. SCHWARTZ. May I say one last thing, Senator Hawkins?

Senator HAWKINS. Surely, Jeff.

Mr. SCHWARTZ. There has been a call for compromise and conciliation and mutual respect. We will try hard—it's hard, when you are in a rage at what you believe was, in some cases, deliberate, conscious decisions made which resulted in the death or injury of your child. It's hard, but we will work on that.

But I do think that there are some plaudits that need to be given, and even where we've differed, as we mightily have on many things, one of the plaudits that needs to be given is to Marge Grant because even though Marge and I have differed on a number of issues, she has been the most early and vocal proponent of the need to do something about this, and we want to acknowledge our debt to her.

Senator HAWKINS. Mrs. Grant testified at my very first hearing in 1982. I'm happy to see you back today and look forward to the summary of your testimony.

Proceed.

Mrs. GRANT. Thank you.

I took the instructions for what they were, that it was to be limited to 5 minutes, so I made it very brief.

I commend you for having this hearing, I am Marge Grant, and I've come here from Beaver Dam, WI.

I welcome the opportunity to provide testimony that shall reflect the views of the Beaver Dam-based DPT SHOT organization, of which I am president. We are a nonprofit group of Determined Parents to Stop Hurting Our Tots, who continue to be actively engaged in telling the other side of the vaccine story to an unsuspecting public.

Our major goal is that of preventing other innocent children from brain damage such as our son Scott suffered 24 years ago from a DTP and polio vaccine, called Quadrigen, made and marketed by Parke Davis & Co., which was proven through the courts to be unreasonably dangerous. Please see exhibit 1, attached.

Let me say at the outset, I can assure you, no one is more concerned about adequate and appropriate compensation for all vaccine-damaged children than we are, and no one needs it more than we do for Scott, who is a nonambulatory, spastic-quadriplegic, mentally retarded young man, who weighs 155 pounds, and whose around-the-clock care is provided in our home by my husband Jim and myself.

However, we cannot selfishly accept compensation for Scott at the expense of hurting other children. With the limited amount of time allowed for oral testimony, I shall give a brief overview of S. 827, touching only on a few of the numerous concerns we have with the bill, with pertinent exhibit references for inclusion in the printed hearing record.

Section 2103: Does this bill give vaccine victims a true option of taking the tort system or compensation program? We don't feel that it does, because the mere filing of a petition for compensation under this program shall constitute a permanent bar against further consideration of any action in the tort system.

In other words, the person who elects to use the compensation system, which shall be mighty tempting for distraught families, such as this lady to my right, cannot turn back and are already barred before true eligibility has been determined. This is too abrupt and, I believe, unfair.

I believe that if they have chosen to take the compensation system, and they are turned down and are not eligible, I think they should still have the choice to take the tort system, although I don't think you should be able to talk about the ineligibility that was determined.

Section 2105: Does the vaccine injury time table allow sufficient time in which all vaccine-induced illnesses shall manifest? We don't believe that it does. As an example, a 7-day period is given for convulsions and residual seizure disorders.

While it is true some convulsions and seizures do manifest within seven days of being vaccinated, it is likewise true that some, such as infantile myoclonic seizures, often occur after the 7th day.

In Scott's case, while he displayed other neurological symptoms the morning after the third shot, the infantile spasms manifested beyond the seventh day. This means those with vaccine-induced acute illnesses, with onsets after the time period for first symptoms listed in the vaccine injury table, will unjustifiably not be eligible for compensation under the provisions of S. 827, as it is presently written.

Our personal research clearly indicates some of the most profoundly disabled children who suffered adversely from vaccines developed infantile myclonic seizures, one of the worst seizure disorders you can have. So I would really hope that this could be included in the bill because I have to tell you, these are very sad cases.

Section 2107: Is the amount of $300,000 to $700,000 a fair compensation for a vaccine-related death? I want to just say that there is no price that can cover the pain that goes with the death or permanent disability of a child, and we think it is not fair, since death does end all pain and suffering and expense for the vaccine recipient; in contrast, the child that is disabled for life suffers on and on, with incessant need of expensive care. I don't think there should be an amount set.

Section 2141: We feel the civil penalty of up to $100,000 for falsification or intentional destruction, alteration, or concealment of any record or report is far too lenient. The wording, "up to," as it is written, we believe vaccine manufacturers could destroy crucial records, in our case they did, and pay as little as a dollar penalty and be vindicated of any wrongdoing.

We agree with the Advocates for a Safe Vaccine who said, "The law must provide that the penalty for destruction of any document is a federal crime." The same should apply to those who disseminate false and misleading information, such as occurred in Wisconsin last year. In this context, I have attached exhibits 2 and 3 which are articles that document how there were 1,903 cases of pertussis reported when, indeed, there had only been 75 at the most.

The Milwaukee Journal did retract this erroneous information, but we can only wonder how many parents were frightened by this magnified number, and needlessly hurried out and took the risk of having their children inoculated with the current highly reactive pertussis vaccine. In contrast, the published report of the FDA/UCLA study was seriously watered-down, not only as to how many adverse reactions occurred but, indeed, that there may well have been hot lots involved, without a recall.

Exhibit 4 is my tabulation of nine cases, taken from the final report of that study, which shows at a glance three specific lots that were repeatedly administered and, indeed, caused severe reactions. In fact, you can see that three of these children died.

The officials that conducted this study deny that any permanent damage resulted in the children that reacted severely. However, it is known by persons in California and elsewhere that at least 4 of the 42 cases that were written up in the final report are dead, and at least another 4 are left permanently damaged; that's the number known of.

I do not find any provisions in S. 827 to mandate a followup of those children that reacted, which I believe is a mighty serious matter and crucial that this be done. I predict, if we knew the truth, the absolute truth, I don't think there would be a question in anybody's mind as to what we ought to be doing about the vaccine. What's more, I don't think we should ask for a safer vaccine—we've got to have a safe vaccine. And if it's safe, we won't need a compensation fund, there won't be any injured children.

I would like to echo the remarks that Senator Stafford made, I thought they were superb. He echoed my sentiments.

Section 2145 contains provisions for what we feel will be a human warehousing. I have seen too much of institutions and what they do, and it's very distasteful to us. I will not comment further on that. Scott is aged 24, and I have kept him out 24 years, and I would like to do so longer, because I don't like institutions.

While the purpose of S. 827 is admirable, and while programs are needed to accomplish the stated purpose, the provisions of S. 827 would layer other complications, including the establishment of another commission, onto an already complex situation. Accordingly, we oppose passage of S. 827, as it is written.

I have to tell you, there are some excellent things in the bill that I would certainly endorse, but I numbered the ones that I couldn't endorse because of the way it is written.

[The prepared statement of Ms. Grant and responses to questions submitted, along with additional material, follow:]

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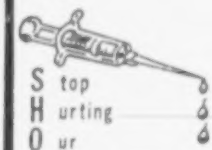

Testimony by: Mrs. Marge Grant, mother of,
Scottie Grant, a DPT - Vaccine - Victim

July 18, 1985

Senator Orrin G. Hatch, Chairman
Senate Committee On Labor And Human Resources
Washington, D.C.

Good morning Mr. Chairman and Committee Members: I am Marge Grant and have come here from Beaver Dam, Wisconsin. I welcome the opportunity to provide testimony that shall reflect the views of the Beaver Dam based DPT SHOT organization, of which I am president. We are a non-profit group of "Determined Parents To Stop Hurting Our Tots," who continue to be actively engaged in telling the "other side" of the vaccine story to an unsuspecting public. Our major goal is that of "preventing" other innocent children from brain damage, such as our son Scott suffered 24 years ago, from a DPT and Polio vaccine, called QUADRIGEN, made and marketed by Parke Davis and Co., which was proven through the courts to be "unreasonably dangerous." (see exhibit 1.) Let me say at the outset, I can assure you, no one is more concerned about adequate and appropriate compensation for "all" vaccine-damaged children, than we are ... and no one needs it more than we do for Scott, who is a non-ambulatory, spastic-quadriplegic, mentally-retarded young man who weighs 155 pounds and whose 'round-the-clock-care, is provided in our home by my husband Jim and myself.

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SCOTTIE GRANT

YOUR CHILD MAY BE NEXT !

Jim & Marge Grant
P.O. Box 543
Beaver Dam, WI 53916

However, we simply cannot selfishly accept compensation for Scott, at the expense of hurting other children. With the limited amount of time allowed for oral testimony, I shall give a brief overview of S. 827, touching only on a few of numerous concerns we have with the bill, with pertinent exhibit references for inclusion of the printed hearing record.

SECTION 2103: DOES THIS BILL GIVE VACCINE-VICTIMS A TRUE OPTION OF TAKING THE TORT SYSTEM, OR COMPENSATION PROGRAM? We don't feel that it does. Because the mere "filing" of a petition for compensation under the program shall constitute a "permanent bar" against further consideration of any action in the tort system. In other words, the person who elects to use the compensation system (which shall be mighty tempting for distraught families to do) cannot turn back and are already barred before true eligibility is even determined. This is too abrupt and unfair.

SECTION 2105: DOES THE VACCINE INJURY TIME TABLE ALLOW SUFFICIENT TIME IN WHICH ALL VACCINE-INDUCED ILLNESSES SHALL MANIFEST? We don't believe it does. As an example, a "7" day period is given for convulsions and residual seizure disorders. While it is true some convulsions and seizures do indeed manifest within 7 days of being vaccinated ... it is likewise true that some, such as infantile-myoclonic-seizures often occur after the 7th. day. In Scott's case, while he displayed other neurologic symptoms the morning after the third shot, the infantile spasms manifested beyond the 7th. day. This means, (those with vaccine induced acute illnesses with onsets after the time period for first symptoms listed in the Vaccine Injury Table), will UNJUSTIFIABLY, "NOT" be eligible for compensation under the provisions of S. 827, as it is presently written. Our personal research clearly indicates some of the more profoundly disabled children who suffered adversely from vaccines, developed infantile-myclonic-seizures.

SECTION 2107: IS THE AMOUNT OF $300,000 TO $700,000 A FAIR COMPENSATION FOR A VACCINE-RELATED DEATH? We think not, since death ends all pain, suffering and expense for the vaccine recipient ... while in contrast, the person that is disabled for life, suffers on and on, with the incessant need of expensive care.

SECTION 2141: We feel the "civil" penalty of "up-to" $100,000 for falsification or intentional destruction, alteration, or concealment of any record or report is far too lenient. As it is written, we believe vaccine manufacturers could destroy crucial records and pay as little as a dollar penalty and be vindicated of any wrong doing. We agree with the "Advocates For A Safe Vaccine," who said the law must provide that the penalty for destruction of any documents is a "Federal Crime." The same should apply to those who disseminate false and misleading information, such as occurred in Wisconsin last year. In this context I have attached exhibits 2, and 3, which are articles that document how there were 1903 cases of pertussis "reported" when indeed there had only been 75 cases at the most, that occurred. The Milwaukee Journal did retract this erroneous information, but we can only wonder how many parents were frightened by this magnified number and needlessly hurried out and took the risk of having their children inoculated with the current highly-reactive pertussis vaccine. In contrast, the published report of the FDA/UCLA study was seriously watered-down. Not only as to how many adverse reactions occurred, but indeed that there may well have been "hot-lots" involved without a recall. Exhibit 4, is my tabulation of 9 cases taken from the final report of that study, which shows at a glance 3 specific lots that were repeatedly administered and indeed caused severe reactions ... in fact, you can see 3 of the infants DIED! The officials that conducted this study, deny that any permanent damage resulted in the children that reacted severely. However, it is known that at least 4 of the 42 cases that are written-up in the final report, are dead and another 4 are left permanently damaged. I do not find any provisions in S. 827 to mandate a follow-up of those children, which I believe is a mighty serious matter and crucial that this be done.

SECTION 2145: Contains provisions for what we feel will be a human warehousing of our handicapped ... and is so distasteful to us, that I shall not make further comment.

While the purpose of S. 827 is admirable and while programs are needed to accomplish the stated purpose, the provisions of S. 827 would layer other complications (including the establishment of another Commission) onto an already complex situation. Accordingly, we oppose passage of S. 827

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WISCONSIN

SCOTT GRANT, an infant under the
age of 14 years, by his father and
natural guardian, JAMES L. GRANT, and
JAMES L. GRANT, individually,

Plaintiffs,

DECISION AND ORDER

v.

Civil Action
No. 71-C-27

PARKE, DAVIS & CO.,

Defendant.

On March 7, 1975, plaintiffs asked this court to apply the doctrine of collateral estoppel against the defendant Parke, Davis & Co. Plaintiffs claim that Parke, Davis should be estopped from relitigating the issues of the defectiveness of defendant's product "Quadrigen" and defendant's negligence in its manufacture, testing, distribution, and failure to warn because those issues have been fully litigated by Parke, Davis in two prior cases, both of which were fully tried and affirmed on appeal. *Stromsodt v. Parke-Davis and Co.*, 257 F.Supp. 991 (D. N.D. 1966); *Parke-Davis and Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969), and *Tinnerholm v. Parke Davis & Co.*, 285 F.Supp. 432 (S.D. N.Y. 1968); *Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48 (2d Cir. 1969). Oral argument on plaintiffs' motion was held on March 21, 1975, and the motion was taken under advisement.

Having fully considered the briefs and arguments of the parties, I believe that plaintiffs' motion must be granted for the reasons expressed by the New York Supreme Court in *Vincent v. Thompson, Parke-Davis & Co.*, Sup. Ct. N.Y. (Nov. 1974).

Continued →

Exhibit -1-

Therefore, under the doctrine of collateral estoppel, this court finds the following with respect to Quadrigen:

* 1. As formulated, manufactured, and distributed by defendant Parke, Davis & Co. prior to and on October 5, November 4, and December 7, 1961, Quadrigen, when it left the possession of the defendant, was defective in that it exposed recipients to an unreasonable danger of damage to the brain and central nervous system.

2. The defendant Parke, Davis & Co. improperly and inadequately tested its product Quadrigen in the face of evidence it was defective before releasing it to the retail market.

3. The defendant Parke, Davis & Co. failed adequately to warn the medical profession of the risks inherent in the use of Quadrigen.

4. By reason of the defendant Parke, Davis & Co.'s formulation, manufacture, and distribution of the dangerously defective product Quadrigen, the defendant's failure properly and adequately to test it and adequately to warn the medical profession of the risks inherent in its use, the defendant Parke, Davis & Co. was negligent.

Dated at Milwaukee, Wisconsin, this 5th day of May, 1975.

John W. Reynolds
U. S. District Judge

State of Wisconsin \ DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH
MAIL ADDRESS
1 WEST WILSON STREET
P.O. BOX 309
MADISON, WISCONSIN 53701

July 18, 1984

Mrs. Marge Grant
915 S. University Avenue
BEAVER DAM WI 53916

Dear Mrs. Grant:

Attached is the news article about pertussis you requested.

Please note that the 1,903 cases reported in Wisconsin for 1983 is clearly in error. This reporting or editing error was a total surprise to me. The correct total of cases reported in Wisconsin for 1983 was 75.

Sincerely,

FOR THE BUREAU OF COMMUNITY HEALTH AND PREVENTION

Jeff Berg
Jeff Berg
Program Advisor
Immunization Program

JB:jsj

Enclosure

THE MILWAUKEE JOURNAL Thursday, May 31, 1984

State 1 of 3 involved in study of disease

Madison, Wis. —UPI— A state health official said Wisconsin was one of three states involved in a study on whooping cough.

Last year 1,903 cases of whooping cough were reported in the state. Immunization official [illegible] Berg said the study would try to find ways to reduce that number. The disease causes extended bouts of coughing.

The study is being coordinated by the Center for Disease Control in Atlanta, Ga., and will also involve the Colorado and Maryland Health Departments.

Exhibit-2

THE MILWAUKEE JOURNAL Accent
Sunday, September 9, 1984

Report to our readers

By Ruth Wilson
Reader Contact Editor

Reader tracked down the right information

Complaints about errors in articles in the newspaper usually come to the paper's attention within a short time. This permits errors to be corrected in a timely fashion.

Last week I received a complaint about an article that was published more than three months ago, but it pointed out an error that still needs to be corrected.

Marge Grant of Beaver Dam referred to a brief article that ran in The Journal May 31. It reported that Wisconsin was one of three states involved in a national study on whooping cough, with a view to finding ways to reduce the number of cases. It stated that in 1983 there were 1,903 cases of whooping cough reported in Wisconsin.

Grant found this figure incredible and did a considerable amount of detective work on her own before contacting The Journal.

From the Centers for Disease Control in Atlanta, Ga., the agency that was to conduct the study, she learned that the number of reported whooping cough cases for the entire United States in 1983 was 2,258, and that the tentative figure for Wisconsin was 71 cases. The director of the Division of Immunization in the Center for Prevention Services suggested that Grant contact the Wisconsin Department of Health and Social Services for precise figures for the state.

From the Bureau of Community Health and Prevention in the Wisconsin department, Grant learned that the total number of whooping cough cases reported in Wisconsin in 1983 was 75.

The article carried by The Journal was provided to the paper by United Press International, and no one was able to trace down where the inflated figure came from.

It clearly was not a typographical error because there is no relationship between that figure and the actual number of cases of the disease in the state. According to the Bureau of Community Health and Prevention, the higher figure doesn't even relate to total communicable diseases reported last year. Until Grant's letter to The Journal, no one had called the error to the attention of the paper or the wire service or requested a correction. Let the error now stand corrected.

Exhibit - 3

MANUFACTURER	LOT #	AGE-SEX	DATE-SHOT	REACTION	DR. - CLINIC	OUTCOME
Lederle	543-126	F 4 mos.	8-29-78	CONVULSIONS	H. Fryer, M.D.	CHRONIC SEIZURE DISORDER
Lederle	543-126	M 4 mos.	1-12-79	103° temp, weak, no suck, lethargic	Plaza Med. Center	"DEAD" 3 days later
Wyeth	64901	F 8½ mos.	4-4-78	JERKING, cried-out during sleep	Dr. W. Garfield	? ? ?
Wyeth	64901	M 4 mos.	1-25-79	LETHARGIC, strange cry, vomiting	Dr. Barlow	? ? ?
Wyeth	64901	M 2 mos.	4-18-79	Fussy for 5 hours after the shot	Dr. Garfield	"DEAD" 82 hrs. later
Wyeth	65501	F 20 mos.	3-22-79	105° - DAZED, FRIGHTENED, SCREAMING	Kaiser - West Los Angeles	? ? ?
Wyeth	65501	F 4 mos.	4-2-79	EXCESSIVE SLEEPING	?	? ? ?
Wyeth	65501	M 18 mos.	4-3-79	103° temp, CONVULSIONS	Kaiser - West Los Angeles	? ? ?
Wyeth	65501	F 2 mos.	4-23-79	SEEMED O.K.	Kaiser - Fontana	"DEAD" 4 days later

FROM CONTRACTOR'S FINAL REPORT OF FDA/UCLA STUDY

Exhibit - 4

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ADDENDUM

By: Mrs. Marge Grant, mother of, Scottie Grant,
a DPT-VACCINE-VICTIM

July 18, 1985

Senator Orrin G. Hatch, Chairman
Senate Committee On Labor And Human Resources
Washington, D.C.

A question arose as I listened to the oral testimony of Mr. Jeffrey Schwartz at the July 18, 1985 hearing on Senate Bill, 827, to which I would very much appreciate knowing whether or not my interpretation is correct, as it is beyond my comprehension and I have not been able to come up with a satisfactory answer.

COMMENT: Mr. Schwartz has been repeatedly accredited for his efforts and participation in putting together S.827

QUESTION: Why did Mr. Schwartz in his "public testimony" before the committee on July 18, take positions in OPPOSITION, to this very bill he co-authored?

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SCOTTIE GRANT

YOUR CHILD MAY BE NEXT !

Jim & Marge Grant
P.O. Box 543
Beaver Dam, WI 53916

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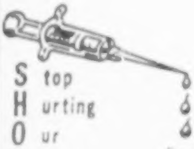

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July 26, 1985

Senator Orrin G. Hatch, Chairman
Senate Committee On Labor And Human Resources
Washington, D.C. 20510

Dear Senator Hatch:

I wish to state for the record: Contrary, to what Mr. Shwartz perceives to be my understanding of the compensation aspect of S. 827, it is indeed my belief, that our son Scott would fit into the injury time table. As would "some" of the other victims, but certainly NOT "all." In fact, I firmly believe many would unfairly be excluded as the bill is written. Because, Section 2104 (c) (2) clearly states: "The 'claims' of a petitioner 'alone' UN substantiated by any other person, by medical records, or by medical opinion, may NOT be an adequate demonstration..." (emphasis mine) In other words, every single claimant shall have to prove, indeed be able to document, that "the first symptom of onset" did actually occur. I can assure you, for a parent to just say it happened at a certain time, is not going to wash ... and it shouldn't!

Before Mr. Schwartz and Ms. Fisher with-held the Donahue mail, (generated by the Grants' appearance on the Phil Donahue show) both admitted to me that they first realized after seeing DPT: VACCINE ROULETTE, that their own childrens' problems may have been due to reactions to the DPT shot. I can tell you most assuredly, our own research amply indicates that the Fisher/Schwartz naivety of this issue are far from isolated cases and most parents do not immediately recognize the reaction as something that must be recorded into the child's medical records. Most unfortunately, many doctors (for whatever reasons) simply do NOT record this crucial information.

Thus, the way S. 827 is written, if enacted into law, will make the vaccine manufacturers and the vaccine administrators ... the "beneficiaries" ... instead of our children, as neither shall be held accountable for damage that was, and will continue to be inflicted upon vaccine recipients.

Determined Parents To Stop Hurting Our Tots, ask you to remember: Just "one more" hurt child ... or "one" vaccine victim, denied compensation ... is "ONE TOO MANY" ... when it's your own child. Only you won't know it, until it happens!

© 1984 M. Grant

SCOTTIE GRANT

Sincerely,
Marge Grant
Mrs. Marge Grant, President
Determined Parents To Stop Hurting
Our Tots, (DPT SHOT)

YOUR CHILD MAY BE NEXT !

Jim & Marge Grant
P.O. Box 543
Beaver Dam, WI 53916

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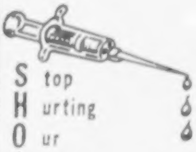

S top
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July 31, 1985

Senator Orrin Hatch, Chairman
Senate Labor and Human Resources Committee
Washington, D.C. 20510

Dear Senator Hatch:

Pursuant to your request I am hereby submitting my answers to the questions your committee asked me to respond to for the July 18, 1985 hearing record on, "Childhood Immunizations: Problems and Options."

QUESTION NO. (1): Why do you think a compensation system is necessary, when we have recourse available through the courts? Could you describe briefly specific problems you have had with the court system that convince you that a government compensation system is necessary?

ANSWER NO. (1): ... PART (A): This presents a false assumption, since we have never endorsed the compensation system as its funding has been proposed, because we firmly believe it is wrong to use the taxing power of the government to take money from the innocent to indemnify the guilty. I believe the term "compensation system" is inappropriately used in the vaccine-victim issue, because true compensation is indeed impossible since it would require "equivalent return," to a person maimed or killed by a vaccine, which obviously cannot be done. As I see it, we must receive adequate financial assistance to enable us to cope with the daily necessities and heavy expense incurred by the incessant care that is required by disabled persons for the rest of their lives.

(CONTINUED)

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SCOTTIE GRANT

YOUR CHILD MAY BE NEXT!

Jim & Marge Grant
P.O. Box 543
Beaver Dam, WI 53916

PART (B): Unfortunately, recourse is not always available through the courts for various reasons. We cannot fault the court system per se, for the loss of our son Scott's suit against Parke Davis. Our specific problems resulted from a "lack of records" brought about by the following episodes: FIRST, despite Scott's pediatrician telling us he administered Parke Davis' vaccine called "QUADRIGEN," to Scott, he negligently failed to record the manufacturer's name and lot numher of the vaccine onto Scott's medical records. SECOND, Parke Davis' attorney, William Roemer, openly admitted to willfully destroying crucial vaccine records. THIRD, while the government vaccine officials under the direction of Dr. Harry Meyer Jr., had assured us they would make requested vaccine records available, they came forth just before trial ... stating that those vaccine records had suddenly disappeared. To use their language, they said those records were here, but have VANISHED! We no longer wonder whose side the FDA is on.

QUESTION NO. (2): All of the legislative proposals that have emerged thus far have included no-fault systems. You seem to support this concept, although your testimony makes clear that you do not believe this is truly a no-fault situation; e.g., you call for a congressional investigation of fault in the industry, pursuant to negligence in developing and marketing safer vaccines. Could you explain this apparent inconsistency?

ANSWER NO. (2): This also presents a false assumption, as we have never been able to find it within our better judgement to be able to support the no-fault concept, because Scott's devastation was unquestionably avoidable. He, along with countless innocent infants were injured due to sheer negligence in the testing and marketing of the grossly defective vaccine, "QUADRIGEN," which is spelled out in the legal document which I attached as exhibit (1) to my July 18, 1985 testimony. If the no-fault system were established, it would vindicate the vaccine manufacturers and vaccine adminstrators for all past, present and future negligence, the effects of which shall be catastrophic, for our children.

(CONTINUED)

QUESTION NO. (3): Is it your view if a compensation fund were established all cases of vaccine-related injury, as defined by a table of compensable events, should be covered, no matter how long ago they occurred? Is such an indefinitely retroactive system not likely to be unrealistic because of its cost?

ANSWER NO. (3): It is my view that some persons are totally disabled because of adverse reactions to injected vaccines. All victims, whether defined by a table of compensable events or not, and regardless of how many years ago these persons were injured, they are nonetheless human beings, suffering every single day of their lives and certainly need to be cared for. We've learned over the past 24 years, that with each passing day the added growth and body weight of an incapacitated person such as Scott, makes it nothing short of dire necessity to receive assistance, in order to continue caring for our loved ones at home, where we want them and they more than deserve to be. Currently, the cost of institutionalization of a person in Wisconsin is about $100.00 a day. That amounts to $36,500.00 a year. Those are tax-dollars, paid to the institutions. Yet, a parent who provides around the clock care, is afforded absolutely nothing. At this cost we have literally saved the taxpayer close to a million dollars by keeping Scott at home. In this context, I suggest a "realistic" fund must be established for the non-institutionalized disabled persons. To grant the parents or guardians who provide equal, if not better care, the same amount that institutions receive. As I understand it, annual budgets appropriate funds to run the various institutions. Since these monies are already appropriated, I believe this would be more of a feasible solution to this matter without the cost becoming UNrealistic.

QUESTION NO. (4): According to your testimony, your goal is to make today's situation different, and better, for tomorrow's children. What would be your view of indemnification by the government of mandatory immunization programs, starting now and retroactive for perhaps two to five years?

(CONTINUED)

ANSWER NO. (4): The mere fact that vaccine manufacturers "knowingly" continued to market unsafe vaccines, despite hurting and killing children, is now their problem and they must not be relieved of being held accountable. The catastrophic effects of the government's indemnification of the swine flu episode, clearly demonstrated that never again, absolutely and unequivocally, should the taxing power of the government take money from the innocent to indemnify the guilty. Persons damaged by the faulty swine flu vaccine wound up fighting themselves with their own tax-dollars, and losing. In no way manner or form should there ever again be indemnification by the government of immunization programs for any period of time, whether the vaccines are mandated or not. Yes, you are right, our goal is indeed for a "better" tomorrow ... a "safe" vaccine ... and above all, no more "hurt" children.

QUESTION NO. (5): In the context of proposals before the committee on environment and public works, representatives of the chemical and other industries have repeatedly made the statement that the risk of injury, without regard to its source, is simply a risk of living in a modern technological society. People are going to become sick, and it is unfair to compensate one set of victims while doing nothing for others. How would you respond to this?

ANSWER NO. (5): People certainly are going to become sick, injured and killed as long as manufacturers continue to be careless and knowingly continue to negligently market unsafe products. Another reason why this bill must not be enacted into law, for if it is, it will provide an initial step for any and all industries to come in for a similar remedy to compensate for their negligence.

QUESTION NO. (6): Do you trust the Department of Health and Human Services to set up a fair and impartial system for settling questions of compensation?

(CONTINUED)

ANSWER NO. (6): Dr. Edward Brandt, Jr., made it very clear in his May 3, 1984 testimony before the Committee On Labor And Human Resources, that we cannot trust the attitude of this bureaucracy, when he said:

> "Despite careful study of individual circumstances, it is often impossible to state with certainty whether or not vaccine has actually played a role in the development of an adverse event. Since virtually all adverse conditions associated with vaccination also occur unrelated to vaccination." (underscoring mine)

Further, one only needs to look at their tarnished track-record to realize, under any condition, can this bureaucracy be allowed to sit in judgement of vaccine-victims. Just to mention a few major cover-ups that employees of this department have successfully conducted in the past:

THE "SV-40" VIRUS: was discovered in polio vaccine by a dedicated research scientist, Dr. Bernice Eddy, clear back in the 1950s and early 1960s. She found when hamsters were injected with polio vaccine, "solid tumors" developed. When she reported this serious matter to her government superiors ... they offered her a trip around the world; didnot permit her to publish this information and simply disregarded her findings. Perhaps worst of all, this contaminated polio vaccine was permitted to be used for at least another four years. Please find attached, exhibit (A), the April 26, 1985 Milwaukee Journal news article which reveals that 98 million Americans received this contaminated polio vaccine, the tragic results of which, now, 25 years later, are showing up in brain-tumor victims. It gives me chills when I think of the future Scott and the millions of other recipients have to look forward to.

QUADRIGEN: Another dangerously defective vaccine approved by this bureaucracy, which by its very composition not only exposed recipients to an unreasonable danger of damage to the brain and nervous system, but indeed, was also contaminated with the SV-40 VIRUS, because Parke Davis had combined polio vaccine with the diphtheria, pertussis and tetanus components in this particular preparation.

(CONTINUED)

THE 1976 SWINE FLU FIASCO: A totally misleading and fraudulent episode, organized and propagandized by the same bureaucracy. Almost a decade ago, American taxpayers were asked to pick up the tab for a public crisis that turned into the infamous swine flu fiasco, which needlessly cost citizens millions of dollars, and in some cases their health and their lives. Again, a highly respected virologist, Dr. J. Anthony Morris, the only federal research scientist to voice an honest opinion in opposition to the program --- was rewarded for his honesty by the FDA firing him. Along with his laboratory animals and revealing research data being destroyed. Dr. Morris worked under the immediate direction of Dr. Harry Meyer Jr., during the swine flu episode. Today, Dr. Meyer holds the powerful postion: Director of FDA's Center for Drugs and Biologicals, which regulates vaccines. Need I say more as to why these powerful government officials cannot be trusted to sit in judgement of compensation for vaccine-damaged children?!

QUESTION NO. (7): Do you accept the industry's claim that the current vaccine is the safest that can be produced and that the manufacturers bear no real liability for any injuries which result from the vaccine, since all such injuries represent the small, but unavoidable risk that accompanies the vaccine?

ANSWER NO. (7): No, the industry's claim that current vaccine is the safest and that injuries represent the small, but unavoidable risk, cannot be accepted. Last year at the WHO meeting in Geneva, the Japanese reported to have developed a pertussis vaccine that is far superior to the currently marketed vaccine in this country. Likewise, Eli Lilly and Co., manufactured and marketed for a while a superior pertussis vaccine, than the highly reactive vaccine that is currently used.

QUESTION NO. (8): The implication hanging over this whole issue is that suits brought by concerned parents like yourselves have caused the current vaccine shortage and the 4000% increase in the price of the DPT vaccine over the last two years. How do you react to that?

(CONTINUED)

ANSWER NO. (8): The so-called vaccine shortage was false and fabricated, and consisted of dangerously misleading information. Dr. Daniel L. Shaw, vice president for Medical Affairs of Wyeth Laboratories, told Congessman Waxman at the December 19, 1984 hearing: "WE have no independent knowledge of any such shortage, [DPT vaccine] but I can tell the subcommittee that we have produced more DTP vaccine this year than last, and will produce more of this vaccine in each of the next 2 years, than we have this year."

QUESTION NO. (9): What is your advice to parents who are taking their children to get DPT shots today?

ANSWER NO. (9): I advise parents to accumulate as much information as possible about the benefits and risks of current DPT vaccine, so as to become fully informed "before" allowing their children to be injected. Then it is up to each individual parent to make an informed decision whether or not the risks outweigh the benefits. I cannot, and, do not, give medical advice.

QUESTION NO. (10): What in your opinion is the single most important thing that we could do to improve our national vaccination program?

ANSWER NO (10): The single most important thing that we can do to improve the vaccination program is to permit an honest person to be Commissioner of the Food and Drug Administration, so that physicians and scientists that are willing to measure honestly, the risks and benefits of vaccines, can do so. Most importantly, the government's regulatory function of vaccines must be taken, out of, the political system.

THE MILWAUKEE JOURNAL Friday, April 28, 1985

Polio vaccine linked to cancer

© Cox News Service

Atlanta, Ga. — A virus that contaminated the polio vaccine given to 98 million Americans in the 1950s and 1960s may play a causative role in some types of brain cancer, according to researchers at the University of Chicago Medical Center.

Although the researchers say their findings "are very preliminary," they have found genetic material from the virus in several brain tumor victims, including three children born to mothers who received the vaccine.

The virus, known to doctors as SV40, has not been found in normal brains, or in people whose cancer spread from elsewhere in the body.

"These results suggest that SV40 may be a good candidate as a possible etiologic agent for human brain tumors," said Jacob R. Rachlin this week, at the annual meeting of the American Association of Neurological Surgeons.

Rachlin said there was not enough evidence to say that virus-contaminated polio vaccine caused the tumors.

Scientists throughout the country have been looking for health effects of the virus since the late 1960s, but Rachlin says the results were "inconclusive" because the researchers used techniques that were not sensitive enough to detect the virus's genetic material.

The virus has been known for years to induce a variety of brain tumors in hamsters inoculated with it.

Now, the Chicago researchers say, it has been found in frozen brain tissue from three of four children who died of medulloblastoma, a soft, infiltrating malignancy of the brain. All four of the children's mothers had received polio vaccine while pregnant.

Rachlin and his colleagues also found the virus's genetic material in two other kinds of brain tumors — in two out of nine people suffering from meningioma, a slow-growing tumor in the tissues surrounding the brain, and in two out of seven people suffering from glioma, another brain tissue tumor.

Exhibit - A

Senator **Hawkins**. Thank you.

Mrs. **Grant**. I would be glad to answer any questions that you have.

I might just add this: So far as the no-fault compensation system is concerned, really, it allows the drug manufacturer and the physician who are indeed responsible for our injured and dead children to be unaccountable. Their attitude will be so we hurt a few, so what?

I think we need legislation, by all means, but I don't feel, as this bill is written, that it should go for passage. I really mean that. I have lived with Scott a long time, and I sure don't want any more hurt children. That's what our title is all about.

Senator **Hawkins**. Yes, I understand.

Mrs. Fisher is with us today. Barbara Fisher, who is a founding member of Dissatisfied Parents Together, who has worked with us from the beginning on the concept of the idea of a safe vaccine, and is author of "DPT: A Shot in the Dark," is seated at the table with Mrs Judd. We welcome you here and commend you for your participation.

I would like to announce that I would like the names and addresses of all those parents who are with us today in the audience given to the Staff Director here so he may give them to the court reporter. We would like your names and addresses in the record, please, and keep you up to date on the progress of this legislation.

[The list of persons from out of town attending the hearing follows:]

List of Parents Attending from out of town
"Childhood Immunization: Problems and Options"
July 18,1985 9:30 a.m.

Judy Glomb
109 Valley Green Drive
Aston, PA 19014

"Our 4 1/2 month daughter died Feb. 14,1985 after her second DPT and second reaction."

Janet and Anthony Ciotoli
107 Pine Knoll Road
Endicott, N.Y. 13760

"Our son, Richard, died 1/13/83 from DPT vaccination at 2 months of age. Death certificate states 'Cause of death : Irreversible shock due to probable DPT vaccine reaction' 33 hours after DPT."

Dick and Velvet Carter
10345 112th St. NO.
Largo, FL 33544

"Our son Chris, age 17, reacted to his 3rd DPT shot and today has uncontrolled seizures and is physically and mentally handicapped."

Gerrie Cohn
14009 Flint Rock Road
Rockville, MD 20853

"16 year old mentally and physically vaccine damaged daughter."

Jonathon and Janice Reed
RD #1 Box 135
Great Bend, PA 17178

"Our son Joshua reacted to his 3rd SPT and now has a chronic and uncontrolled seizure disorder."

Carol A. Hall
10111 Henry Court
Manassas, V.A. 22110

"Our 3 year old daughter reacted to her 2nd DPT and now has physical and mental problems."

Debbie and Steve Pusateri
1422 Kirkwood Road
Baltimore, MD 21207

"Our son died approximately 6 hours after his first DPT shot after more than 4 hours of intense screaming."

Mrs. Claudia M. Bias
3332 - Martin Luther King Jr. Ave. S.E.
Washington, D.C. 20032

"My son John has brain damage and left with a disease call Bullous Pemphgoid."

Donna Middlehurst and Jeff Schwartz
2626 Colston Dr.
Ceny Chase, M.D. 20815

"Our daughter Julie had a seizure within 8 hours of her 3rd DPT shot. She suffered from a seizure disorder and other problems for 3 years, and died as a result of a seizure in 1984."

Mrs. Haviland Abbot
1121 Guilford Ct.
McLean, VA 22101

"2 1/2 year old daughter is vaccine damaged. Went into seizures 2 hours after her 3rd shot."

Barbara Loe Fisher
2571 Windbreak Drive
Alexandria, VA 22306

"My 7 year old son reacted to his 3rd DPT shot (severe local reaction) and on his 4th DPT shot he had shock/collapse, was unconscious for 6 hours, and also had a severe systemic reaction. He was left with multiple learning disabilities as a result of this 4th shot."

Denise Judd
711 North, 390 East
American Fork , Utah 84003

"My son was 2 months old when he got his 1st DPT shot. He slept deeply for a day, eventually could not open his mouth to eat, had convulsions, went into cardiac arrest and died. By the time he died, he had brain damage and paralysis."

Senator HAWKINS. Senator Dodd has joined us today.

The number of Senators joining us is indicative of the interest on behalf of the members of this committee.

Do you have an opening statement? Welcome.

Senator DODD. I do, Madame Chairman. And because I know you are anxious to move things along, let me, first of all, apologize to our witnesses. We had the Chairman of the Federal Reserve Board up here all morning.

I will just submit my opening statement for the record, and any of the questions that I may have for the parents I will submit to you, and they can respond in writing. I would appreciate that.

Thank you very much.

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR DODD

This hearing relates to a problem that I have a deep interest in--the balancing of the public's needs for important products with the compensation of people injured by those products. I have developed a proposal—Senate Amendment No. 16 to S. 100—which addresses the problem in general. Here we are dealing with an important piece of that problem—what to do when certain drugs that serve an important public function also severely injure some.

I find the administration reponse entirely unacceptable and shortsighted. The problem of the availability of vaccines is crucial. So is the compensation of people hurt by those drugs. It is entirely unacceptable to leave the injured people and their relatives to care for them. On the other hand, the compensation paid to those people should be limited to only those actually injured by the drugs and should be for a limited amount.

Because the legislatures have not come up with fair compensation schemes, it has been left up to the courts to jerry rig theories for providing awards. These theories pervert the tort law and still leave many victims uncompensated, victims compensated in radically different fashions and, under all circumstances, victims waiting far too long for recoveries.

It is time we recognized that if the Congress doesn't face up to this issue, the courts will. And if we leave it up to the courts, we will continue to have the problems I just outlined and manufacturers will be harmed as well as victims. If we take care of the losses of victims through a compensation system, without the major involvement of attorneys, we will be able to afford to pay at least four times as many injured persons as the tort system pays with the same dollars.

Madam Chairman, I hope we will be able to work together, along with the people representing the injured, the doctors and the manufacturers—and, hopefully, the administration—to devise a system that is fairer to all parties, predictable and at a legitimate cost to all.

Senator HAWKINS. Any questions?

Senator PELL. No.

Senator HAWKINS. We thank this panel for appearing today. We are really very grateful for your participation in the drafting of this bill.

Our next panel will be a panel that represents the Administration. We will hear testimony from the Department of Health and Human Services and the Department of Justice.

We are pleased that both administration witnesses were members of the recent Cabinet Council Working Group on Vaccine Supply and Liability, and welcome their insights into the process of that working group's deliberations.

I understand the administration's legislative proposal was developed based on the discussions of the Cabinet Council Working Group and on their advice to the Secretary of Health and Human Services.

Dr. Mason, it is always a pleasure to welcome you to the Labor and Human Resources Committee. You, certainly, provide us with great expertise on the vaccine issue in your capacity as CDC Director, as well as in your present role as Acting Assistant Secretary for Health—did I get that right, Acting Assistant Secretary for Health?

Dr. **Mason**. Right.

Senator **Hawkins**. We have heard great things about you and the superb job you are doing as acting head of the Public Health Service. I commend you for that. We are anxious to receive your views and those of the Department of HHS on the various issues relating to vaccines and childhood immunization.

Dr. Mason, we will hear from you first, if you have a statement, a 5-minute summary, please.

STATEMENTS OF DR. JAMES O. MASON, ACTING ASSISTANT SECRETARY FOR HEALTH AND DIRECTOR, CENTERS FOR DISEASE CONTROL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. ALAN HINMAN, CENTERS FOR DISEASE CONTROL; AND ROBERT WILLMORE, DEPUTY ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION, DEPARTMENT OF JUSTICE, WASHINGTON, DC

Dr. **Mason**. Thank you. I do, and I will abbreviate it for you. Madame Chairman, I am here with Dr. Alan Hinman, who is the head of our Immunization Program at CDC, and I have other representatives from the Public Health Service here, as well.

I am pleased to appear before you today to discuss issues related to childhood immunization, one of our most successful public health programs of prevention.

This committee is well aware of the spectacular reduction in disease and death that have resulted from the widespread use of vaccines in childhood.

A chart I have over here illustrates the decrease in morbidity from disease for which we now routinely immunize children before they enter school. In this country, diphtheria has been essentially eliminated, and whooping cough, or pertussis, is now under control, as well as the other diseases that are mentioned there.

We have realized enormous cost savings with immunizations. Not unexpectedly, however, this remarkable progress has had some costs. While immunization represents one of the most cost-effective and cost-saving public health measures available, vaccines are neither perfectly safe nor perfectly effective. And even though scientists are working to develop safer and more effective vaccines, there will almost always be a few individuals who may be harmed by a procedure designed to help them.

I would like to point out, however, that the number of adverse effects known to be caused by vaccines is small. Those that do occur are not thought to be the result of a defective vaccine but, rather, are due to a rare reaction to the vaccine components by a specific individual.

Vaccine production is strictly regulated in the United States by the Food and Drug Administration to assure that defective products are not distributed.

The lawsuits filed against vaccine manufacturers are not based on improperly made products. The number of lawsuits against vaccine manufacturers has increased dramatically, accompanied by a similarly dramatic rise in the amount of recoveries in individual cases.

Last July, Connaught Laboratories, Inc., cited difficulty in obtaining liability insurance as the primary reason that they stopped accepting new orders for DTP vaccine. Wyeth Laboratories had earlier announced its departure from the market. This left Lederle Laboratories as the sole commercial source.

Lederle subsequently contracted with Wyeth to purchase Wyeth-produced vaccine, and adequate supplies appeared to be available until Lederle encountered production problems in late November 1984.

This precipitated a shortage of DTP vaccine. To stretch the small supply of vaccine as far as possible, without compromising immunity, the Public Health Service recommended, in December, that health care providers defer the 18-month and 4-to-6-year-old doses of DTP vaccine until more adequate supplies became available.

A compounding problem threatening the supply of DTP vaccine at the time was an announcement by Lederle that their insurance was due for renewal July 1, 1985, and that they felt that they might have problems in obtaining adequate coverage. These events led HHS Secretary Margaret Heckler, as Chair Pro Tempore of the Cabinet Council on Human Resources, to establish a working group on vaccine supply and liability.

I served as chairman, and I would like to place in the record a copy of the working group's report, if that would be permissible.

Senator HAWKINS. I believe this is it.

[The following was received for the record:].

Report of the Cabinet Council on Human Resources

Working Group on VACCINE SUPPLY AND LIABILITY

EXECUTIVE SUMMARY

In November 1984, a shortage of the DTP (diphtheria, tetanus, pertussis) vaccine occurred in the United States. This situation arose from the precipitous withdrawal of two of the three vaccine distributors from the market and a production problem encountered by the remaining one. All three manufacturers cited problems in obtaining insurance for the vaccine because of lawsuits that were filed following publicity about adverse side effects allegedly due to the pertussis component of the vaccine. In addition, the two other vaccines—MMR (measles, mumps and rubella) and oral polio—used to immunize children before school entry are supplied by single manufacturers and thus a similar shortage could occur. To study the current problem that may jeopardize one of this Nation's most successful public health programs—the protection of American children against vaccine-preventable diseases--Secretary of Health and Human Services Margaret Heckler, as Chair Pro Tempore of the Cabinet Council on Human Resources, established a Working Group on Vaccine Supply and Liability.

The Working Group included representatives from the Departments of Treasury, Justice, and Health and Human Services, the Office of Management and Budget, the Council of Economic Advisors, the Office of Science and Technology Policy, and the White House. It met four times between March 5 and March 26, 1985. Working Group members had preliminary discussions with both vaccine manufacturers and insurance underwriters. They considered the economics of vaccine cost and the legal issues surrounding compensation for vaccine-related injuries.

The Working Group identified four general problems. Two of these problems--vaccine supply and vaccine cost--are intertwined and demand immediate resolution. The two other problems were whether injured individuals have any significant difficulty in obtaining compensation in an equitable and timely manner, and possible disincentives to manufacturers to develop new and improved vaccines. The group felt it needed more information from the manufacturers to adequately understand these problems. In view of the urgency of the situation, the group agreed to focus primarily on vaccine supply and cost.

The root causes of the vaccine supply and liability problems were viewed by the Working Group as a chain of events. Each year vaccines cause a certain number of injuries, even though they are manufactured and administered properly. Injured persons sue the manufacturers, and sometimes recover large judgments. There have been instances of particularly large awards for punitive damages, which in many States are not insurable, and for non-economic damages such as pain and suffering. These factors, in turn, lead to an inability to calculate the cost of vaccine-related risk (and the related inability to obtain insurance), and a perceived lack of return by manufacturers on their investment. As a result, the manufacturers are abandoning this product line with the possibility that there will be no manufacturers of childhood vaccines.

The Working Group carefully examined eight options and recommends that the Administration seek the enactment of legislation to ban punitive damages in vaccine-related injury cases and to place a generous but reasonable cap on all non-economic damages.

From its review, the Working Group found that punitive and non-economic damages are the large, and generally unpredictable part of many vaccine-related awards. There is little justificiation for punitive damages in cases of vaccine-related injury since vaccines are strictly regulated under Federal law. The group also concluded that a cap on non-economic damages (pain and suffering, mental anguish, emotional distress, etc.) was reasonable if set at a generous level. Non-economic damages are based on subjective judgment, and have a significant effect on vaccine cost. By contrast, although economic damages vary somewhat from State to State and case by case, they generally fall within a broad range for particular types of injuries.

The Working Group felt that this option would ensure a supply of vaccines because it will make the size of the awards much more predictable, and thus will allow insurance underwriters to calculate risk for childhood vaccines. In addition, since there is no limitation on the amount of economic loss compensation a plaintiff can receive, there is no risk that any plaintiff might be deprived of necessary medical, custodial, or rehabilitative services.

Following their deliberations, the Working Group met with both vaccine manufacturers and the American Academy of Pediatrics to discuss the recommendation. Both groups said that banning of punitive damages and a cap on non-economic damages were of some help, but it was not the option either preferred. The manufacturers would prefer an overall cap on awards and the American Acadmey of Pediatrics would prefer establishing a no-fault compensation system for victims.

The Working Group also discussed additional provisions that might be added to a legislative proposal encompassing the recommendation. An Advisory Commission on Childhood Vaccines was posed as an option that might begin to address the problem of determining whether injured individuals have any significant difficulty in obtaining compensation in an equitable and timely manner. An important feature of this provision, and one requiring legislation, is the Commission's ability to subpoena records from manufacturers on settlement of vaccine-related injury claims. The Working Group noted that this information was not available to them and is critical to any discussion about whether there is a need for creating a compensation system.

UPDATE

Following the meetings and deliberations of the Working Group, Connaught Laboratories announced that it had worked out insurance arrangements and is resuming full distribution of DTP vaccine in the United States. Connaught is supplying the vaccine to the Centers for Disease Control for use in public sector clinics at a cost of $2.21 a dose, about $0.60 less than Lederle. Although Lederle continues to have a 90 day cancellation clause on its insurance, it continues to distribute vaccine it produces as well as that manufactured by Wyeth.

As a result of these developments, there is currently enough DTP vaccine to meet U.S. needs. On April 26, the Immunization Practices Advisory Committee and the Committee on Infectious Diseases of the American Academy of Pediatrics recommended that U.S. physicians resume administration of the complete DTP schedule and implement recall procedures for children under seven years of age whose fourth and fifth DTP doses were deferred.

Although the vaccine supply problem appears to be solved, at least temporarily, the root cause driving the problems of vaccine supply and cost remain. The Working Group anticipates that the number of lawsuits filed against manufacturers will continue to increase and that those who insure vaccine manufacturers will continue to be concerned about the unpredictability and size of awards. In addition, there is still a problem of single distributors for the other childhood vaccines.

Therefore, the Working Group stands by its recommendation, which seeks to provide a permanent solution to the vaccine supply and cost problems. The recommended solution to seek the enactment of legislation to ban punitive damages in vaccine-related injury cases and to place a generous but reasonable cap on all non-economic damages addresses the root cause of these problems. In addition, the Advisory Commission on Childhood Vaccines suggested by the Working Group will begin to address the related problem of determining whether injured individuals have any significant difficulty in obtaining compensation in an equitable and timely manner. Meanwhile, the Department of Health and Human Services will expedite development of an improved pertussis vaccine.

Report of the Cabinet Council on Human Resources

Working Group on VACCINE SUPPLY AND LIABILITY

April 1985

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Report of the Cabinet Council on Human Resources

Working Group on
VACCINE SUPPLY AND LIABILITY

Issue

The supply of vaccines against childhood illnesses is seriously threatened. Within the past year, two of the three manufacturers of the diphtheria, tetanus, and pertussis (DTP) vaccine have stopped distribution. As a result of this precipitous withdrawal of manufacturers from the marketplace, and because of a recent production problem encountered by the remaining manufacturer, a temporary shortage of the DTP vaccine occurred.

Although the Working Group was unable to obtain precise information, it learned that well over 100 personal injury lawsuits have been filed by parents who claim that their children have been harmed by the DTP vaccine; specifically, by the pertussis (whooping cough) component of the vaccine. All but a few of these lawsuits were filed since the broadcast of a 1982 television program, "DPT: Vaccine Roulette."

This sudden increase in tort litigation has made insurers reluctant to offer adequate liability coverage to the manufacturers of the DTP vaccine. Although the number of personal injury lawsuits can be predicted within a broad range, the open-ended nature of the damages potentially recoverable in such lawsuits has led many underwriters to conclude that the risk of writing such insurance policies cannot be calculated with any degree of reasonable certainty. The manufacturers, in turn, have indicated their unwillingness to produce the DTP vaccine without adequate insurance coverage. As a result, two manufacturers have stopped distributing the DTP vaccine. The remaining distributor and its insurers are currently discussing whether DTP liability insurance will be renewed as of July 1, 1985.

Although the current focus is on the supply of the DTP vaccine, the supply of the other childhood vaccines could also be affected in the near future.

The OPV (oral polio) and the MMR (measles, mumps, and rubella) vaccines are each supplied by single manufacturers, who also have a number of vaccine-related, personal injury lawsuits pending against them.

Deliberations of the Working Group

Because the foregoing problem threatens one of the Nation's most successful public health programs, Secretary Heckler established a Cabinet Council on Human Resources Working Group on Vaccine Supply and Liability. The members of the Working Group are listed in Appendix 1. At the Working Group's first meeting on March 5, 1985, the Secretary expressed her deep concern about the need to ensure a continued, reliablesupply of the childhood vaccines. She requested that the Working Group examine the following issues and report back to her with recommendations and strategies by April 1, 1985:

- Identify the problems in vaccine supply and liability.
- Identify the root causes of the problems.
- Identify and assess potential options, including those already under consideration and others if appropriate.
- Identify the appropriate Federal role in the various options.
- Recommend the best approach and describe the strategies needed to carry out that approach.

The Working Group met four times between March 5th and March 26th. Working Group members had preliminary discussions with both manufacturers and insurance underwriters. They considered the economics of vaccine cost, as well as the legal issues surrounding compensation for vaccine-related injuries. They reviewed vaccine compensation programs established by six foreign countries and three States. The Working Group identified several problems and root causes of these problems. They considered eight options with various degrees of Federal involvement, narrowed the discussion down to four, and chose one as the most appropriate.

Background

Since 1970, the Federal Government has provided direction and leadership to State and local health agencies in implementing childhood immunization programs.

As a result, all 50 States and the District of Columbia currently have laws requiring immunization before entering school. For school year 1983-1984, 98 percent of all children entering school were immunized for measles and rubella and 97 percent were immunized for mumps, polio, diphtheria, pertussis, and tetanus.

Childhood immunization has contributed greatly to the health of our Nation by severely limiting, and in some cases virtually eliminating, illnesses that formerly killed or permanently disabled thousands of children (Table 1). The following facts demonstrate the success of this effort:

- Measles has been all but eliminated from the United States, except for cases brought in from other countries.
- Record lows have been reported in five of the last six years for measles and rubella, and eight of the last nine years for mumps.
- Only four cases of polio, three cases of tetanus, and no cases of diphtheria were reported in 1984 for children under age 15.
- In 1934, the peak year for whooping cough in the United States, more than 7,500 children died from the disease. In 1982, four children died from whooping cough.

Cost-benefit analyses of the childhood immunization programs demonstrate substantial net benefit, indicating that these programs contribute significantly to containing the cost of health care, as well as to the quality of life in the United States. It is estimated that the cost-benefit ratio of the pertussis vaccine is 1:11.1, the cost-benefit ratio for measles, mumps, and rubella immunization given in combination is 1:14.4, and that the ratio for polio immunization is 1:10.3 (Figure 1). This amounts to an estimated savings of more than $2 billion since 1963 for measles and about $1 billion per year for polio. The Centers for Disease Control (CDC) estimates that over 57 million cases of measles and 19,100 cases of mental retardation have been averted, and that 5,700 children's lives have been saved as a result of measles immunization alone.

Although these vaccines are highly effective, they are neither perfectly safe nor perfectly effective. Each year, some children suffer adverse reactions to vaccines.

Development of Improved Pertussis Vaccine

Substantial efforts are underway to improve the pertussis vaccine. The currently used pertussis vaccine contains whole cells, including cell wall components and endotoxins, to which some individuals develop adverse reactions. These reactions can be severe. An improved vaccine would use only the material conferring immunity (antigens) to whooping cough.

New pertussis vaccines have been developed in Japan, and were introduced there for general use in late 1981. Because these vaccines contain only a few antigens, they theoretically should cause significantly fewer side-effects than the conventional vaccines, and are alleged to be as effective.

However, neither efficacy nor lowered risk of serious adverse reactions has been demonstrated satisfactorily. There is much interest in these new vaccines in the United States in both the public and private research sectors.

The National Institutes of Health (NIH) currently supports two Vaccine Evaluation Centers where limited clinical testing to determine the initial safety and effectiveness of such new vaccines is possible. An experimental DTP vaccine prepared by Wyeth is currently under test in these centers. Larger scale field trials would be required, however, to demonstrate general efficacy and to identify and establish the frequency of less common side effects. Because the childhood immunization program in the United States has been so successful, the incidence of whooping cough is too low to conduct such a field trial here.

CDC, NIH, and the Food and Drug Administration (FDA) are collaborating with the World Health Organization and Swedish health officials in designing a clinical trial of one of the Japanese pertussis vaccines and perhaps another candidate acellular vaccine. This trial, which will be supported partially by CDC, NIH, and the Agency for International Development, will provide valuable new information about the safety and effectiveness of these new vaccines, and may hasten the evaluation of other new vaccines being developed for use in the United States. Public Health Service (PHS) officials estimate that an improved pertussis vaccine may be available in three to five years.

Efforts to develop an improved pertussis vaccine are detailed in Appendix 2.

Public and Congressional Concerns

Several relatively recent legal developments have made it much easier for persons injured by a vaccine to obtain compensation from the manufacturer or provider of the vaccine. Some of these developments involve general doctrines of product liability law; other developments relate to principles that specifically apply to vaccines, pharmaceuticals, and similar products. An important precedent was set for such suits in the Reyes v. Wyeth Laboratories case, a 1974 decision in which $200,000 was awarded to a child paralyzed by oral polio vaccine on the basis of the manufacturer's failure to warn the recipient in a public health clinic setting.

More recently, the rare but serious adverse reactions to the pertussis vaccine came to the public's attention through an hour-long program entitled "DPT: Vaccine Roulette," which aired in Washington, D.C., in April 1982. Later, the "Today" show aired segments of the program nationally. It alleged that the vaccine causes brain damage, retardation, convulsions, and death. It asserted that these adverse reactions are due to the crudeness of the pertussis component of the DTP vaccine.

As a result of this publicity, Members of Congress received hundreds of calls from concerned individuals, and a special interest group representing parents of vaccine damaged children (Dissatisfied Parents Together) was formed.

When the television program aired in 1982, three U.S. commercial manufacturers were distributing the DTP vaccine. Wyeth and Squibb-Connaught withdrew from the market last year, Squibb-Connaught citing its inability to obtain reasonably priced liability insurance. Lederle presently is the sole distributor of the pertussis vaccine. As noted, Lederle's liability insurance is due to be renewed July 1, 1985. The Working Group was told that the status of that renewal is uncertain.

From its discussions with vaccine manufacturers, the Working Group estimates that more than 100 lawsuits have been filed alleging injury from pertussis vaccinations. These lawsuits are based on a variety of legal theories against the manufacturers and providers of the vaccine. Although the number of such lawsuits obviously is a matter of concern to the potentially liable parties and to their insurers, of even greater concern is the open-ended and unpredictable level of damages available in such lawsuits. This latter concern is at the core of the insurability problem currently threatening the continued availability of the pertussis vaccine.

Three types of damages are available to a plaintiff suing for an injury resulting from a vaccination: compensation for economic loss (medical, custodial, and rehabilitation expenses, lost earnings, etc.); compensation for non-economic injuries (pain and suffering, mental anguish, etc.); and punitive damages. The first of these three elements of damages, although varying from State to State and from case to case, generally falls within a broad range for particular types of injuries. Such economic loss compensation can be substantial—some serious childhood brain damage cases, for example, have resulted in economic damage awards in excess of $1 million.

Damage for non-economic injury and punitive damages, in comparison, are open-ended and virtually unpredictable. Such damages often reflect the subjective judgment of the jury, and can be multiples of the damages awarded for economic loss. This almost total unpredictability has led the manufacturers, providers, and insurers of the pertussis vaccine to conclude that they cannot ascertain the monetary risk associated with pertussis vaccine injury litigation.

Some people have expressed concern about the process for compensating those harmed by vaccines required by State laws. In the 98th Congress, bills were introduced in the Senate (Hawkins—S. 2117) and House (Waxman—H.R. 5810) which would have established no-fault compensation arrangements funded by a surcharge on vaccine doses with the Federal Government covering the shortfall. These bills were supported by the American Academy of Pediatrics and Dissatisfied Parents Together. Hearings were held in the Senate Labor and Human Resources Committee and the House Energy and Commerce Subcommittee on Health and the Environment.

The Administration testified in opposition to these proposals, criticizing in particular the fact that the proposed program was not an exclusive remedy, the broad list of compensable conditions, the level of payment established, and the retroactivity provision. Subsequently, the Department of Health and Human Services, the Department of Justice, and the Department of the Treasury transmitted bill reports to Senator Hatch in opposition to S. 2117. Senator Hawkins reintroduced an expanded and clarified version of the bill (S. 827) on April 2, 1985, and tentatively has scheduled hearings for early May. Congressman Waxman is expected to introduce a bill in the near future.

The American Medical Association (AMA) presented a draft bill on vaccine compensation at a December 1984 House Energy and Commerce Health Subcommittee hearing. The AMA bill would have established an exclusive administrative system for those injured as a result of a childhood immunization. The AMA has since withdrawn its proposal.

In February, Lederle circulated among the Administration, Members of Congress, and involved interest groups an administrative compensation proposal. A key feature of this proposal is an overall cap on the size of a vaccine injury award. In addition, the Lederle proposal would establish an initial no-fault arbitration system which claimants would have to pursue prior to filing a personal injury lawsuit. Although no manufacturer would be required to submit to such arbitration, any arbitration results would be binding on the liable manufacturer, and the manufacturer would not obtain the benefit of the overall cap unless it consented to such arbitration. Congressman Madigan introduced a slightly modified version of this proposal (H.R. 1780) on March 27, 1985.

The inability to provide an adequate supply of vaccines for American children poses a significant public health problem. Based on its review of background material and preliminary discussions with manufacturers and insurance underwriters, the Working Group concluded that the current vaccine shortage is real and that although a temporary solution might be worked out between the manufacturers and insurers, the problem is likely to arise again since the underlying problem still exists.

Problems

The Working Group identified four general problems related to vaccine supply and liability. Two of these problems--vaccine supply and vaccine costs—are intertwined and require immediate resolution. The two other problems reviewed by the Working Group were whether injured individuals have any significant difficulty in obtaining compensation in an equitable and timely manner, and possible disincentives to manufacturers to develop new and improved vaccines. The Working Group agreed that more information from manufacturers was needed to fully understand the extent of these problems.

PROBLEM 1: VACCINE SUPPLY

The three childhood vaccines are each supplied by a single distributor. Merck Sharp & Dohme manufactures and distributes MMR vaccine. Lederle is currently the sole U.S. distributor of OPV and the DTP vaccine. Because of potential problems in supply created by the existence of only a single distributor, funds were provided to CDC in 1983 to begin purchasing childhood vaccines for a rotating Federal stockpile. CDC plans to build up the stockpile gradually over several years with the goal of providing a six-month supply of national needs. The national needs are 19 million doses per year for DTP, 4 million doses for MMR, and 16.8 million doses for OPV. CDC began stockpiling MMR and OPV because in 1983 there was only one supplier for each of these vaccines and a backup supply was considered essential. The sudden withdrawal of manufacturers from the DTP market was not anticipated, and a stockpile of DTP can not be established until more vaccine becomes available. Figure 2 shows the status of the vaccine stockpile.

The current shortage of the DTP vaccine arose in November of last year when Lederle encountered a production problem with several lots of vaccine. If current production of the DTP vaccine continues and the insurance issue is resolved, adequate supplies should be available by mid to late 1985. Until then, physicians in both the public and private sectors have been asked to defer the two DTP vaccine doses given to older children.

PROBLEM 2: VACCINE COST

The price of all childhood vaccines has increased dramatically in recent years (Figure 3). The OPV and MMR vaccines have nearly tripled in price since 1978. Since 1982, the price of the DTP vaccine has risen from 11 cents per dose to the current price of $2.80 per dose—a 25-fold increase in two years. Much of this increase in price appears to be related to increased liability exposure.

Approximately half of the childhood vaccines are administered by public sector sources in the United States. Most of these vaccines are paid for by Federal funds through a CDC grant program (Table 2).

The Working Group determined that the problems of vaccine supply and cost are directly related and, accordingly, must be solved together.

PROBLEM 3: COMPENSATION OF INJURED INDIVIDUALS

State laws require children to be immunized before they enter school. Although these laws were enacted to protect society from preventable infectious diseases that have the potential of killing or severely disabling thousands of children each year, some vaccines have side-effects which harm a small number of individuals each year.

In the United States, those injured by vaccines must resort to the tort system, which in theory requires them to prove negligence or other fault on the part of the manufacturer or provider of the vaccine. While many such claims are settled quickly, the process can at times be slow and expensive.

Three States--California, Massachusetts, and Michigan--provide an alternative system for compensation of vaccine-related injuries. Massachusetts and Michigan manufacture their own vaccine, and can be sued in their capacity as manufacturers. In Massachusetts, recovery is limited to $100,000. California established an immunization compensation program in 1977 which provides administrative compensation up to $25,000. Claimants may obtain compensation under this system as well as through the tort system. Only three claimants have filed under the California administrative program to date. In addition, six foreign countries (Denmark, West Germany, France, Japan, Switzerland, and the United Kingdom) have compensation systems for persons injured as a result of vaccine immunization.

The Working Group agreed that the primary Federal concern at present should be to ensure the continued supply of vaccines, and that the compensation of vaccine injured persons should receive more study before deciding what changes in the current system, if any, are warranted.

PROBLEM 4: DISINCENTIVES TO MANUFACTURERS TO DEVELOP IMPROVED VACCINES

At present, there are single suppliers for each of the childhood vaccines. When there is only a single supplier, the buyer has no control over cost; and with no competition, the incentive to develop improved products is sharply reduced.

Incentives for manufacturers to stay in or enter the vaccine market are adversely affected by the alleged low profitability. Some manufacturers have asserted that they remain in the market only because of the benefits of vaccines to society. But over the past decade, eleven manufacturers have left the vaccine market.

The Working Group agreed that the lack of multiple childhood vaccine manufacturers is a serious problem. The Working Group views development of an improved pertussis vaccine as critical to a long-term solution of the current problem, and believes that attracting additional manufacturers to the market will significantly improve the likelihood that a safer pertussis vaccine will be developed as expeditiously as possible.

Root Causes

The root causes of the vaccine supply and liability problems can be viewed as a chain of events. Modern vaccines are safe and effective, but they are neither perfectly safe nor perfectly effective. Each year vaccines cause a small number of injuries, even though they are manufactured and administered properly.

The injured persons sue the manufacturers, and sometimes recover very large judgments. There have been instances of particularly large awards for punitive damages (which in many States are not insurable) and for non-economic damages such as pain and suffering.

These factors, in turn, lead to an inability to calculate the cost of vaccine-related risk (and the related inability to obtain insurance), and a perceived lack of return by manufacturers on their investment. As a result, the manufacturers are abandoning this product line, with the possibility that there will be no manufacturers of childhood vaccines.

ROOT CAUSE 1: SAFETY OF VACCINES

Vaccine production is tightly regulated under Federal law. Not only is a license required for distribution, but each batch of vaccine produced by a manufacturer must meet government specifications before being released for use. In spite of appropriate manufacturing techniques, adverse events occur. Even with an improved vaccine there would be some adverse reactions simply because of the large number of doses administered. Overall, CDC estimates that less than 100 severe adverse effects related to the childhood vaccines occur each year.

In some cases, the cause of adverse effects is relatively easily identified: vaccine-associated paralytic polio can be identified by the uniqueness of the virus. Other adverse reactions are difficult to differentiate from background events that occur during childhood. This is particularly true of events allegedly attributable to the pertussis component of the DTP vaccine.

ROOT CAUSE 2: LITIGATION

Several recent legal developments have greatly expanded vaccine manufacturers' liability to consumers, thereby reducing the financial incentives to market a vaccine and increasing the difficulty of obtaining insurance against compensation claims. The most far-reaching of these developments is the scope of manufacturers' duty to warn of inherently dangerous properties of the vaccine. Some courts have held that vaccine manufacturers have a duty to warn consumers directly, and cannot rely on warnings given by those administering the vaccine.

In addition, several courts have held, in other contexts, that a manufacturer must warn of hazards that were unknown and even unknowable at the time of manufacture. If this theory were applied in the vaccine context, vaccine manufacturers could be held liable for adverse effects that were not and could not be known at the time of distribution.

In discussions with manufacturers and insurers, Working Group members confirmed that the number of lawsuits alleging harm due to childhood vaccines is increasing dramatically. They also confirmed that the size of many of the recent vaccine awards is quite large, especially for punitive and other non-economic damages.

ROOT CAUSE 3: INABILITY TO CALCULATE THE COST OF VACCINE-RELATED RISK

The inability to calculate the cost of vaccine-related risk is primarily a result of the unpredictability of the size of tort awards, particularly the punitive and non-economic components of these awards. Manufacturers have informed the Working Group that this is the root cause of their inability to obtain insurance for distribution of the DTP vaccine.

ROOT CAUSE 4: PERCEIVED LACK OF RETURN ON INVESTMENT

It has been suggested that the low profitability of vaccines has caused several manufacturers to leave the market. As noted, over the past decade, eleven manufacturers have stopped distributing childhood vaccines. Many of these departures occurred before the onset of the current major vaccine liability problems.

The issue of profitability is further complicated by the limited market for vaccines, as well as by the prominence of a single, large purchaser (the Federal Government) of vaccines.

Options

The Working Group examined eight options representing a wide range of possibilities. They include:

1. Establish a no-fault government compensation system that establishes causation through the use of tables.

   This option is similar to proposals introduced by Senator Hawkins and Congressman Waxman in the 98th Congress, and by the proposal recently introduced by Senator Hawkins in the 99th Congress (S. 827).

2. Establish a no-fault arbitration compensation system with an overall cap on awardable damages.

   This option is similar to the Lederle proposal, as introduced by Congressman Madigan (H.R. 1780).

3. Cap non-economic and prohibit punitive damage awards within the existing tort system.

   This option would leave the existing tort system for compensation of vaccine-related cases in place, but would make the size of the award more predictable by prohibiting punitive damages and capping non-economic damages.

4. Modify liability in the existing tort system by changing the standard of fault.

   This option would legislate certain fault standards which would have to be met to hold a manufacturer or provider liable for a vaccine-related injury. This approach is similar to a proposal under consideration in Congress with respect to product liability law in general (S. 100, the "Kasten bill").

5. Establish a system of reinsurance by the Federal Government.

   This option would relieve the manufacturers from searching for liability coverage beyond a certain level. Discretionary authority for reinsurance by HHS is contained in S. 827.

6. Have the government purchase and distribute the vaccines and assume liability.

This option may be effective but only with special legislation, similar to what was done with the swine flu vaccine.

7. Have the government purchase and distribute vaccines on a cost-plus basis with manufacturers retaining liability.

8. Negotiate and persuade the manufacturers and insurers to find options not necessitating legislation or the Federal Government's assumption of liability.

The Working Group reviewed all the above options. After rejecting the other options for a variety of reasons, the group concentrated its attention on Options 2, 3, 6, and 8.

Discussion of Considered Options

OPTION 2: NO-FAULT ARBITRATION SYSTEM WITH OVERALL CAP

An arbitration system with an overall cap on the amount of available damages, such as the Lederle proposal, has certain advantages:

- It will ensure a continued supply of vaccines by capping awards at reasonable levels, thus making manufacturers' exposure more predictable and, accordingly, more insurable.
- It does not, at least initially, involve government compensation payments or administrative costs.
- It offers parents of children harmed by vaccines an alternative system for obtaining compensation that hopefully will be less arduous than the sometimes long, complex procedures of tort litigation.

The Working Group considered several possible amendments to the Lederle proposal. These included limiting the program to the DTP vaccine, incorporating a five-year sunset clause (to allow for development of an improved pertussis vaccine), placing a reasonable cap on attorneys' fees, and limiting the medical conditions which would be covered.

The proposal has certain disadvantages, however, that persuaded the Working Group that it is not the best available option:

- By establishing an administrative compensation system, the proposal creates the framework for Federal funding should the private sector participants be unwilling or unable to fund the program in future years.

- There has not been adequate research or analysis of the consequences of a no-fault compensation system. The Working Group was extremely concerned that the precedent of no-fault compensation could be extended to other areas such as professional liability or product liability where such an approach may be highly undesirable.

- In certain instances, an overall cap might deprive claimants of the funds to pay for necessary medical or custodial treatment or rehabilitation. If the overall cap were established on the basis of a "worst case" injury, however, the cap might be so high as to be meaningless for the vast majority of cases. If established at that level, the overall cap may not, in fact, solve the vaccine supply problem.

- The Working Group felt that if an administrative compensation system is to be adopted, it should be an exclusive remedy, and that lack of exclusivity may make an administrative compensation system unworkable in the long term.

OPTION 3: CAP CERTAIN DAMAGE AWARDS WITHIN THE EXISTING TORT SYSTEM

This approach would bar all punitive damages in childhood vaccine-related injury cases and place a generous but reasonable cap on all non-economic damages.

From its review of vaccine-related personal injury cases, the Working Group found that punitive and non-economic damages are a large, and generally unpredictable part of many awards. For example, $8 million of a recent $10 million award in a polio vaccine case consisted of punitive damages. Punitive damages are intended to punish the defendant. There is little justification for such damages in cases of vaccine-related injury cases, since vaccines are strictly regulated under Federal law.

The Working Group noted that many legal commentators and judges have long criticized the award of punitive damages in mass tort cases, and felt these criticisms particularly applicable in vaccine-related injury cases. There is a broad consensus that punitive damages are inappropriate in vaccine-related injury cases. Both current legislative proposals would bar punitive damage awards for their proposed compensation systems. In addition, the Madigan bill would bar such awards in State tort lawsuits.

Moreover, to the extent that punitive damages are passed on to the government and to the non-subsidized vaccine consumer (which is likely where there is a single or a handful of manufacturers), it is senseless to "punish" the government or consumers.

The Working Group concluded that a cap on non-economic damages (pain and suffering, mental anguish, emotional distress, etc.) was reasonable if set at a generous level. Non-economic damages are based on subjective judgment, and have a significant effect on vaccine cost. The cost of such damages (as with punitive damages) may be passed on largely to the government and to non-subsidized consumers of vaccines in the form of higher vaccine prices. The Working Group was also concerned that without such a cap, juries might effectively use non-economic damages to award punitive damages. The Working Group noted that the current legislative proposals all cap awards of non-economic damages for their proposed compensation systems, and the Madigan bill would cap such awards in State tort lawsuits.

Punitive and non-economic damages are open-ended and, therefore, are the most unpredictable part of personal injury awards. Although economic damages vary somewhat from State to State and case to case, they generally fall within a broad range for particular types of injuries.

The Working Group found the following advantages in this proposal:

- It will ensure a continued supply of vaccines because it will make the size of the awards much more predictable, and thus will allow insurance underwriters to calculate risk for childhood vaccines.
- There is no limitation on the amount of economic loss compensation a plaintiff can receive. Accordingly, there is no risk that any plaintiff might be deprived of necessary medical, custodial, or rehabilitation services.
- It will simplify and expedite the tort litigation process by making it pointless to build an elaborate case for the sake of establishing punitive damages. Consequently, it is likely that tort cases will be settled more quickly and at significantly less litigation cost in the form of attorneys' fees and pre-trial expenses.
- It retains incentives for manufacturers to find safer vaccines because they are still subject to potentially substantial economic damages for injuries.
- It represents the least intrusive degree of Federal involvement in State affairs, while at the same time protecting the overriding Federal interests in ensuring an adequate supply of childhood vaccines.

The Working Group recognizes that this proposal may not be perceived as satisfactory to parents who want a compensation program, and will be actively opposed by lawyers who represent plaintiffs in tort cases. Both are well-organized interest groups.

OPTION 6: GOVERNMENT PURCHASE AND DISTRIBUTION

The Working Group considered the possibility of the government purchasing DTP vaccine under contract and distributing it to both public and private sources in the United States. This was discussed as a contingency plan to assure a continued supply of pertussis vaccine if legislation to solve the problem in a more permanent way is not enacted in time.

This option would allow plaintiffs to sue the government under the Federal Tort Claims Act, which does not allow recovery of punitive damages or permit jury trials. However, this solution could lead to very costly judgments against the United States. In addition, under current law, it would not prevent suits directly against manufacturers. The Working Group discussed the alternative approach of direct Federal manufacturing of the DTP vaccine. Plaintiffs would then have to sue the government for damages under the Federal Torts Claims Act.

OPTION 8: NEGOTIATION AND PERSUASION

This approach offers several advantages. Most importantly, no precedents would be set with respect to Federal solutions for other difficult compensation situations. It also would not interfere with evolution of tort law, with whatever corrections develop from inappropriate findings of fault and excessive awards.

After preliminary discussions with the manufacturers and insurers, however, the Working Group concluded that it probably would be impossible to reach an assured long-term solution to the supply problem simply through negotiation and persuasion.

Recommendation

> The Working Group recommends Option 3, that the Administration seek the enactment of legislation to ban punitive damages in vaccine-related injury cases and to place a generous but reasonable cap on all non-economic damages.

In addition, the Department of Health and Human Services will accelerate efforts to develop an improved pertussis vaccine.

The Working Group met with both manufacturers and the American Academy of Pediatrics to discuss the recommended option. Both groups said the banning of punitive damages and a cap on non-economic damages were of some help, but it was not the option either preferred. The manufacturers would prefer an overall cap on awards, and the American Academy of Pediatrics would prefer establishing a no-fault compensation system for victims.

The Working Group also discussed additional provisions that might be added to a legislative proposal encompassing the recommendation. An Advisory Commission on Childhood Vaccines was posed as an option that might begin to address the problem of determining whether injured individuals have any significant difficulty in obtaining compensation in an equitable and timely manner. An important feature of this provision, and one requiring legislation, is the Commission's ability to subpoena records from manufacturers on settlement of vaccine claims. The Working Group noted that this information was not available to them and is critical to any discussion about whether there is a need for creating a compensation system.

APPENDIX 1

CABINET COUNCIL ON HUMAN RESOURCES
WORKING GROUP ON VACCINE SUPPLY AND LIABILITY

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APPENDIX 2

ADDITIONAL MATERIAL ON PERTUSSIS VACCINE STUDIES

- Three-Dose vs. Four-Dose Schedule Investigation: The present schedule of DTP—four doses at approximately 2, 4, 6, and 18 months of age—has been derived from several studies performed in the United States and elsewhere. For program reasons (decreasing the number of visits), and safety concerns (fewer exposures to vaccine), there would be advantages to limiting the number of doses of DTP if there were no compromise in immunity. A study to compare the effectiveness of three vs. four doses of DTP administered in the first 18 months of life is underway in Philadelphia.

- Michigan Department of Public Health has a contract initiated by NIH in September 1983 to develop a new pertussis vaccine for use in the United States. The vaccine is patterned after the Japanese product. The contractor has successfully isolated and purified two protein components and is presently characterizing them.

- Wyeth Laboratories: Wyeth has purchased an improved pertussis vaccine from a Japanese pharmaceutical firm, combined it with tetanus and diphtheria toxiods, and repackaged it under terms of an Investigational New Drug Application (IND). The vaccine has been distributed to the two NIH-supported Vaccine Evaluation Units for safety and effectiveness studies. Results in children are encouraging. The incidence of reactions was considerably less than that observed with the old vaccine. Further testing is underway.

- NIH (Rocky Mountain Laboratory): Efforts are in progress to isolate specific proteins of the pertussis organism important in the disease process. Using recombinant DNA techniques, it is anticipated that this approach may result in the identification and isolation of the DNA coding for the pertussis toxin.

- Squibb-Connaught Laboratories: Squibb-Connaught is in the process of producing and testing a vaccine similar to the new Japanese product. Squibb-Connaught has completed safety testing and dose-response studies. The information has been submitted to the FDA with a request for an IND.

- Lederle Laboratories: In addition to its currently marketed vaccine, Lederle also has committed to develop and manufacture an improved pertussis product. Lederle plans to submit an IND for its new vaccine in 1985.

Table 1

COMPARISON OF MAXIMUM & CURRENT MORBIDITY VACCINE-PREVENTABLE DISEASES

Diseases	Maximum Cases		1984	% Change
	Number	Year		
Diphtheria	206,939	(1921)	1	–100.00
Measles	894,134	(1941)	2534	– 99.72
Mumps	152,209	(1968)	2921	– 98.08
Pertussis	265,269	(1934)	2187	– 99.18
Polio	21,269	(1952)	4	– 99.98
Rubella	5,686	(1969)	745	– 98.71
Congenital Rubella Syndrome	20,000	(1964–5)	4	– 99.98
Tetanus	601	(1948)	64	– 89.35

Table 2

ESTIMATED COST OF CHILDHOOD VACCINES TO BE PURCHASED BY THE FEDERAL GOVERNMENT IN 1985

Vaccine	Cost (millions)
Polio	6.5
Measles–Mumps–Rubella	13.7
Diphtheria–Tetanus–Pertussis	8.0
	28.2

Figure 1

HIGH COST-BENEFIT RATIOS OF IMMUNIZATION

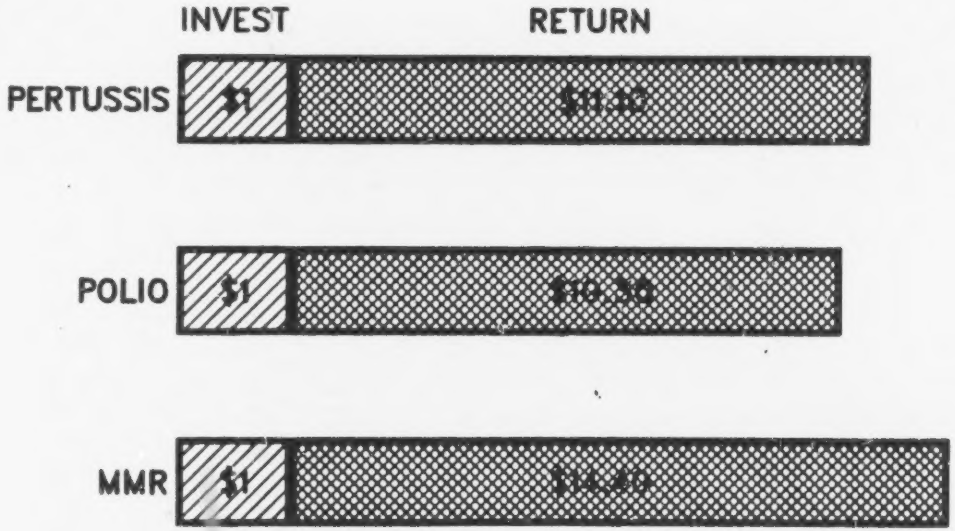


Figure 2

STATUS OF CDC VACCINE STOCKPILE
March 1985

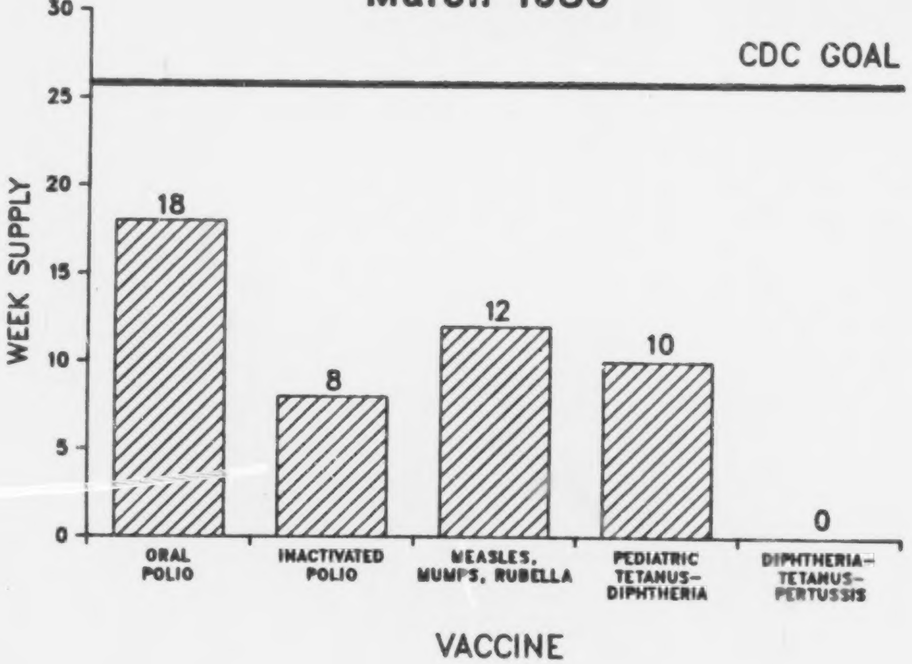
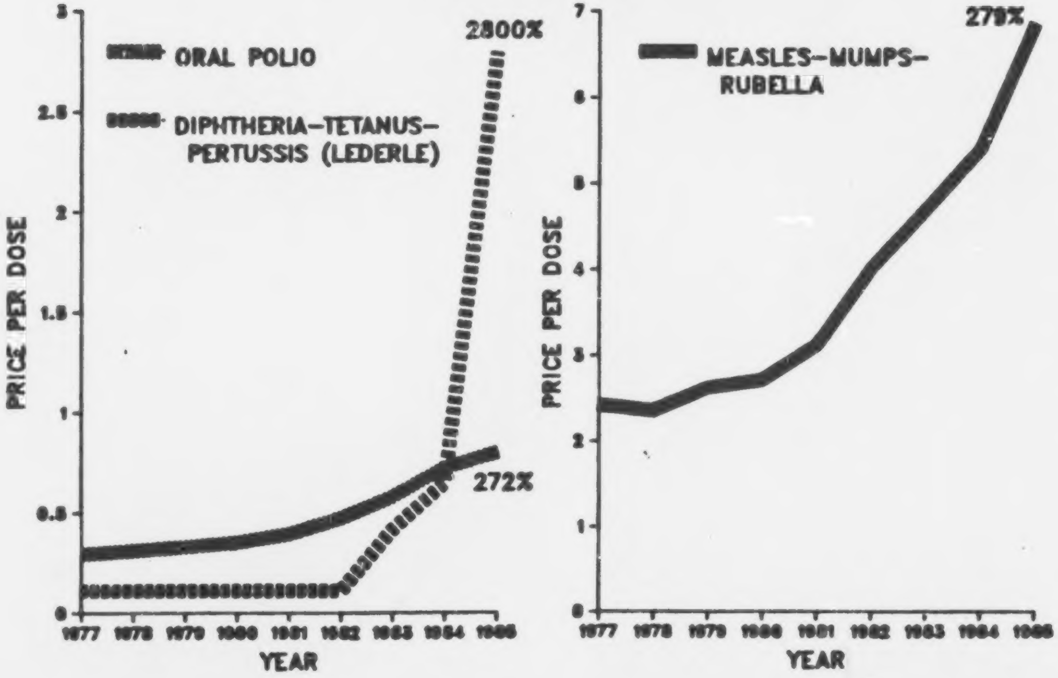


Figure 3

CDC VACCINE CONTRACTS
1977-1985



Dr. MASON. Working group members had preliminary discussions with both vaccine manufacturers and insurance underwriters. They considered the economics of vaccine costs and the legal issues surrounding compensation for vaccine-related injuries.

The working group identified four basic problems. Two of these problems, vaccine supply and vaccine cost, are intertwined and demand immediate resolution. The two other problems were whether injured individuals have any significant difficulty in obtaining compensation in an equitable and timely manner, and whether there were disincentives to manufacturers to develop new and improved vaccines.

In view of the urgency of the situation, the group agreed to focus primarily on vaccine supply and costs. The working group saw the root cause of the problem as a chain of events. Each year, vaccines cause a certain number of injuries even though they are manufactured and administered properly.

Injured persons sue the manufacturers and sometimes recover large judgments. There have been instances of particularly large awards for punitive damages, which in many States are not insurable, and for noneconomic damages, such as pain and suffering.

These factors, in turn, lead to an inability to calculate the cost of vaccine-related risk, and an alleged lack of return by manufacturers on their investment. As a result, some manufacturers are abandoning this product line.

From its review, the working group found that punitive and noneconomic damages are the large and generally unpredictable part of many vaccine-related awards. As Mr. Willmore will explain in more detail, there is little justification for punitive damages against a manufacturer in cases of vaccine-related injuries.

The group also concluded that a cap on noneconomic damages, such as pain and suffering, was reasonable if set at a generous level.

After carefully examining a number of options, the working group recommended enactment of legislation to ban punitive damages in vaccine-related injury cases, and to place a generous but reasonable cap on all noneconomic damages.

This option would place no cap on compensation of economic damages. The working group felt that this option would ensure a supply of vaccine because it would make the size of the awards more predictable and, thus, would allow insurance underwriters to calculate risk for childhood vaccines. Since there is no limitation on the amount of economic loss compensation a plaintiff can receive, there is no risk that a plaintiff might be deprived of necessary medical, custodial, or rehabilitative services.

We believe that if the administration's proposal were enacted, this would be a major step toward a permanent solution to the vaccine supply and cost problem.

The problem of whether injured individuals have any significant difficulties in obtaining compensation in an equitable and timely manner is much more difficult to address. The proposed Advisory Commission on Childhood Vaccines would be able to collect the information needed to arrive at a rational decision concerning legislation to establish compensation systems.

We cannot support the compensation approach in S. 827. We have previously testified about our concerns with the concept of legislating causality through a table of compensable events.

In addition, we are extremely concerned about the precedent of no-fault compensation for other areas, such as professional liability or product liability, where such an approach might be highly undesirable. Another concern is that S. 827 is not an exclusive remedy.

I would like to give you a brief report on the current and near future supply of the DTP vaccine.

Connaught Laboratories, Inc., announced that it had worked out insurance arrangements and will resume full distribution. Connaught is also supplying vaccine for use in public sector clinics. Lederle continues to distribute vaccine. There is currently enough DTP vaccine to meet U. S. demands.

Although the immediate vaccine supply problem appears to be solved, at least for the time being, the root cause driving the problems of vaccine supply and cost remain.

This chart over here [indicating] shows the dramatic increases in the price of all childhood vaccines in recent years. These increases are expected to continue.

I would like to emphasize that the present resolution of the DTP shortage is temporary at best. If the present litigation climate continues, insurance coverage problems will recur, and we can expect to see this reflected in vaccine cost and availability.

Furthermore, the supply of DTP is not the only one that is in jeopardy. There have been a number of oral polio vaccine lawsuits filed.

In 1983, to guard against interruptions in supply of vaccines, the Public Health Service began to establish a stockpile of childhood vaccines. The goal was to have on hand at all times a 6-month supply of these vaccines. Because there were three manufacturers of DTP at that time, it was felt less likely that an interruption in DTP supply might occur, and efforts were placed on purchasing oral polio and measles-mumps-rubella [MMR] vaccines. Consequently, the shortage in November 1984 occurred when no DTP vaccine had yet been placed in the stockpile.

I am pleased to announce that last month the Public Health Service established a contract with Connaught Laboratories to purchase nearly 4 million doses of DTP vaccine for the stockpile.

This chart [indicating] shows the current status of the stockpile. With the funds available through fiscal year 1985, the stockpile will reach approximately 45 percent of the desired 6-month supply. Although the stockpile will get us through a temporary shortage, it is not a permanent solution.

A word about efforts to develop a safer pertussis vaccine. One of the recommendations of the working group was to accelerate the already existing efforts to improve the pertussis vaccine.

It is hoped that severe adverse events associated with the vaccines can be reduced or even eliminated Although there is no complete assurance that liability concerns will be totally eliminated, the development of improved vaccines should be a major positive step.

Attempts to prepare an improved pertussis vaccine have a long history, spanning over 40 years. These past attempts have been impeded by technological limitations, but recently science and technology have advanced to enable the development of acellular vaccines.

Acellular pertussis vaccines have been in widespread use in Japan since 1981, and are reported to be associated with fewer and less serious adverse effects than current whole cell vaccines.

We are not certain that the Japanese experience is directly translatable to our situation. The published data from the Japanese concerning efficacy are limited, and previous attempts by U.S. scientists to obtain information have been unsuccessful.

I have recently written to the Japanese Minister of Health, requesting permission to send a delegation of U.S. scientists to Japan to discuss, in detail, issues relating to acellular vaccine safety, efficacy, and testing.

Clinical efficacy trials can be best performed in countries with high pertussis incidence and well-developed laboratory systems. Sweden offers a unique opportunity. The Swedish National Bacteriological Laboratory in Stockholm has been searching for an effective acellular pertussis vaccine.

The Swedish Laboratory has already chosen for the trial an acellular vaccine produced by the Biken Institute of Osaka University, Osaka, Japan. A clinical efficacy trial of this vaccine is scheduled to begin in Stockholm, Sweden, in February 1986. It is anticipated that the trial will be completed by September 1987.

The Public Health Service has provided a significant portion of the funding for this trial and has expended considerable efforts to have another acellular vaccine considered for study.

The two candidates currently under consideration for inclusion in the Stockholm trial contain pertussis toxoid only. One of the products is made by the Biken Institute and the other is made by the Michigan Department of Public Health, under contract with the National Institutes of Health.

The Stockholm trial will provide information on the efficacy of at least one, and possibly two, acellular vaccines and will permit an evaluation of the more frequent types of adverse reactions.

An additional effort is being planned by scientists from the Laboratory of Development and Molecular Immunity of the National Institute of Child Health and Human Development.

The Committee on Vaccine Development of the British Medical Research Council has formed a subcommittee to plan an efficacy trial of new pertussis vaccines in the United Kingdom. Public Health Service officials have had discussions with them about possible candidate vaccines. The earliest starting date for such a trial would be mid to late 1986.

Other trials may be necessary to answer important questions concerning optimal vaccine composition, age at first vaccination, number of doses, and interval between doses. Efforts are presently under way to identify possible sites for such studies.

In summary, I have told you of the reduction in morbidity and mortality that has resulted from widespread use of vaccines to prevent childhood diseases in this country. We all agree that it is essential to assure a continued supply of these important products. We have recently weathered a crisis in DTP vaccine supply.

However, the root causes that precipitated this crisis still exist. In addition, the other vaccines used to immunize children in the United States are currently supplied by single manufacturers, and these manufacturers also face liability exposure that may lead to difficulties in obtaining adequate levels of insurance.

The administration's proposal would ensure the continued supply of vaccines by minimally modifying the existing tort system. We would seek to eliminate punitive damages in vaccine-related injury cases, and place a $100,000 cap on noneconomic compensatory damages. There would be no limitation on the amount of economic loss compensation a plaintiff can receive.

At present, we do not have adequate information about current sources of compensation, and we believe action on any compensation proposals at this point would be premature. A proposed advisory commission should provide us with the needed information.

Finally, HHS has accelerated its efforts to support the development and testing of improved pertussis vaccines.

Madame Chairman, this concludes my prepared statement. We would be pleased to answer any questions you might have.

[The prepared statement of Dr. Mason and responses to questions submitted for the record follow:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

STATEMENT OF

JAMES O. MASON, M.D., Dr.P.H.

ACTING ASSISTANT SECRETARY FOR HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

JULY 18, 1985

Mr. Chairman and members of the Committee, I am pleased to appear before you today to discuss issues relating to childhood immunization, one of our most successful public health programs of prevention. In my remarks, I will discuss the deliberations of the Cabinet Council Working Group on Vaccine Supply and Liability, the status of the vaccine stockpile, and our accelerated efforts to develop an improved pertussis vaccine.

This Committee is well aware of the spectacular reductions in disease and death that have resulted from widespread use of vaccines in childhood. This chart illustrates the decrease in morbidity from diseases for which we now routinely immunize children before they enter school. In this country, diphtheria, a disease which formerly killed thousands of children each year, has been essentially eliminated. And whooping cough or pertussis, a disease which afflicted several hundred thousand children during epidemic years, is now under control.

We have realized enormous cost-savings with immunizations. For every dollar we spend on immunizations for polio, more than ten dollars are saved in medical costs. Similar savings are realized with the other childhood vaccines. We estimate that over 57 million cases of measles and 19,100 cases of mental retardation have been averted, and 5,700 children's lives have been saved because of measles immunization alone.

Not unexpectedly, however, this remarkable progress has had some costs. While immunization represents one of the most cost-effective and cost-saving public health measures available, vaccines are neither perfectly safe nor perfectly effective. And even though scientists are working to develop safer and more effective vaccines, there will almost always be a few individuals who may be harmed by a procedure designed to help them.

I would like to point out, however, that the number of adverse effects known to be caused by vaccines is small. Those that do occur are not thought to be the result of a defective vaccine but rather are due to a rare reaction to the vaccine components by a specific individual. Vaccine production is strictly regulated in the United States to assure that defective products are not distributed. As part of the regulatory process, the Food and Drug Administration reviews and approves individual lots of vaccine before they can be released for commercial distribution. The possibility of distributing a vaccine that does not meet Federal requirements is exceedingly small.

The lawsuits filed against vaccine manufacturers are not based on improperly made products. Rather, several legal developments have greatly expanded vaccine manufacturers' liability to consumers. As a consequence of these and other developments, the number of lawsuits against vaccine manufacturers has increased dramatically, accompanied by a similarly dramatic rise in the amount of recoveries in individual cases. The three commercial manufacturers who have distributed the diphtheria and tetanus toxoids and pertussis (DTP) vaccine in the past few years have informed us that 140 suits were filed in the State tort systems in the seven-year period 1978-1984. More than half of them were filed in 1984. Many of the claims were for unspecified amounts. For those claims in which amounts were specified, the average amount requested per suit was $46.5 million in 1984, compared to about $10 million in 1978.

DEVELOPMENT OF TEMPORARY DTP SHORTAGE

Last July, Connaught Laboratories, Inc. cited difficulty in obtaining liability insurance as the primary reason they stopped accepting new orders for DTP vaccine. Wyeth Laboratories had earlier announced its departure from the market. This left Lederle Laboratories as the sole commercial source of DTP vaccine. Lederle subsequently contracted with Wyeth to purchase Wyeth produced vaccine, and adequate supplies for the Nation appeared to be available until Lederle encountered production problems in late November 1984. This precipitated a shortage of DTP vaccine in the United States. To stretch the small supply of vaccine as far as possible without compromising immunity, the Public Health Service recommended in December that health care providers defer the 18-month and 4-6 year old doses of DTP vaccine until more adequate supplies became available.

A compounding problem threatening the supply of DTP vaccine at that time was an announcement by Lederle that their insurance was due for renewal July 1, 1985, and that they felt that they might have problems in obtaining adequate coverage. These events led HHS Secretary Margaret Heckler, as Chair Pro Tempore of the Cabinet Council on Human Resources, to establish a Working Group on Vaccine Supply and Liability.

DELIBERATIONS OF THE WORKING GROUP

The Working Group included representatives from the Departments of Treasury, Justice, and Health and Human Services; the Office of Management and Budget; the Council of Economic Advisors; the Office of Science and Technology Policy; and the White House. It met four times between March 5 and March 26, 1985. I served as Chairman.

Working Group members had preliminary discussions with both vaccine manufacturers and insurance underwriters. They considered the economics of vaccine costs and the legal issues surrounding compensation for vaccine related injuries.

The Working Group identified four basic problems. They determined that two of these problems--vaccine supply and vaccine cost--are intertwined and demand immediate resolution. The two other problems were whether injured individuals have any significant difficulty in obtaining compensation in an equitable and timely manner and whether there were disincentives to manufacturers to develop new and improved vaccines. The group felt that in order to adequately understand these issues, more study and additional information from the manufacturers would be needed. In view of the urgency of the situation, the group agreed to focus primarily on vaccine supply and cost.

The Working Group saw the root causes of the problem as a chain of events. Each year, vaccines cause a certain number of injuries even though they are manufactured and administered properly. Injured persons sue the manufacturers, and sometimes recover large judgments. There have been instances of particularly large awards for punitive damages, which in many States are not insurable, and for non-economic damages such as pain and suffering. These factors, in turn, lead to an inability to calculate the cost of vaccine-related risk (and the related inability to obtain insurance), and alleged lack of return by manufacturers on their investment. As a result, some manufacturers are abandoning this product line.

From its review, the Working Group found that punitive and non-economic damages are the large, and generally unpredictable, part of many vaccine-related awards. As Mr. Willmore will explain in more detail, there is little justification for punitive damages against a manufacturer in cases of vaccine-related injuries. The group also concluded that a cap on non-economic damages, such as pain and suffering, was reasonable if set at a generous level. Non-economic damages are based on subjective judgment and have a significant effect on vaccine costs. By contrast, although economic damages vary somewhat from State to State and case by case, they generally fall within a broad range for particular types of injuries.

After carefully examining a number of options, the Working Group recommended enactment of legislation to ban punitive damages in vaccine-related injury cases and to place a generous but reasonable cap on all non-economic damages. This option would place no cap on compensation of economic damages. The Working Group felt that this option would ensure a supply of vaccines because it would make the size of the awards more predictable, and thus would allow insurance underwriters to calculate risk for childhood vaccines. In addition, since there is no limitation on the amount of economic loss compensation a plaintiff can receive, there is no risk that a plaintiff might be deprived of necessary medical, custodial, or rehabilitative services.

DISCUSSION OF CURRENT LEGISLATIVE PROPOSALS

The Administration's proposal is an outgrowth of the Working Group's deliberations. We believe that if enacted this would be a major step toward a permanent solution to the vaccine supply and cost problems. It would make liability exposure predictable, thus permit manufacturers to establish costs for vaccines. At the same time, because there is no cap on the amount of economic loss compensation, plaintiffs can be assured that they can receive the necessary medical, custodial, and/or rehabilitative services.

The problem of whether injured individuals have any significant difficulties in obtaining compensation in an equitable and timely manner is much more difficult to address. Despite discussions with manufacturers and insurers, the Working Group was unable to obtain reliable data about the outcome of claims and suits filed regarding vaccine damage, particularly with regard to the amounts of out-of-court settlements reached. The proposed Advisory Commission on Childhood Vaccines would be able to collect the information needed to arrive at a rational decision concerning legislation to establish compensation systems. This Commission would differ from others which have studied the compensation problem in the past in that it would have authority to subpoena records, including those from manufacturers on settlement of vaccine-related injury claims.

We cannot support the compensation approach in S. 827. We have previously testified about the shortcomings of S. 2117, the predecessor of S. 827. Although some of the shortcomings have been modified, others remain. We have previously testified about our concerns with the concept of legislating causality through a table of compensable events. This approach does not easily allow for revision as new scientific knowledge becomes available. In addition, we are extremely concerned about the precedent of no-fault compensation for other areas such as professional liability or product liability where such an approach might be highly undesirable. Another concern is that S. 827 is not an exclusive remedy. Lack of exclusivity may make any compensation system unworkable in the long run.

CURRENT VACCINE SUPPLY SITUATION

I would like to give you a report on the current and near future supply of the

DTP vaccine. On April 25, 1985, Connaught Laboratories, Inc. announced that it had worked out insurance arrangements and would resume full distribution of DTP vaccince in the United States. Connaught is also supplying vaccine under contract to the Centers for Disease Control for use in public sector clinics. Lederle continues to distribute vaccine it produces as well as that manufacturered by Wyeth.

As a result of these developments, there is currently enough DTP vaccine to meet U.S. needs. On April 26, physicians were advised by the Public Health Service to resume administration of the complete five dose DTP schedule and implement recall procedures for children under seven years of age whose fourth and fifth DTP doses were deferred.

Although the immediate vaccine supply problem appears to be solved, at least for the time being, the root cause driving the problems of vaccine supply and cost remain. This chart shows the dramatic increase in the price of all childhood vaccines in recent years. The oral polio and the measles, mumps and rubella (MMR) vaccines have nearly tripled in price since 1978. Since 1982, there has been more than a 20-fold increase in the price of DTP. The cost has risen from 11 cents per dose to the current price of $2.80, and we expect the price will rise again in the next year.

I would like to emphasize that the present resolution of the DTP shortage is temporary at best. If the present litigation climate continues, insurance coverage problems will recur, and we can expect to see this reflected in vaccine cost and availability. Furthermore, the supply of DTP is not the only one that is in jeopardy. There have been a number of oral polio vaccine lawsuits filed. In fact, oral polio vaccine lawsuits have resulted in the largest jury verdicts. Recently, a claimant in Washington State was awarded $4 million for damages suffered from the polio vaccine. A jury awarded another claimant $10 million, of which $8 million was for punitive damages. Currently, Lederle is the sole U.S. manufacturer and distributor of this vaccine.

STATUS OF THE STOCKPILE

In 1983, to guard against interruptions in supply of vaccines, the Public Health Service began to establish a stockpile of childhood vaccines. The goal was to have on hand at all times a six-month supply of these vaccines. Because there were three manufacturers of DTP vaccine at that time, it was felt less likely that an interruption in DTP supply might occur, and efforts were placed on purchasing oral polio and MMR vaccines. These latter vaccines were produced by single manufacturers, were more expensive than DTP, and were likely to be subject to significant price increases. Consequently, the shortage in November 1984 occurred when no DTP vaccine had yet been placed in the stockpile. I am pleased to announce that last month, the Public Health Service established a contract with Connaught Laboratories, Inc. to purchase nearly four million doses of DTP vaccine for the stockpile. This is about a ten-week supply.

This chart shows the current status of the stockpile. With the funds available through FY 1985, the stockpile will reach approximately 45 percent of the desired six-month supply. Further purchases will be made over the next few years to complete the stockpile.

Although the stockpile will get us through a temporary shortage, such as the one which occured in November, it is not a permanent solution to the vaccine supply and cost problems.

EFFORTS TO DEVELOP A SAFER PERTUSSIS VACCINE

One of the recommendations of the Working Group was to accelerate the already existing efforts to improve the pertussis vaccine. It is hoped that severe adverse events associated with pertussis vaccines can be reduced or even eliminated. Although there is no complete assurance that liability concerns will be totally eliminated, the development of improved vaccines should be a major positive step. Consequently, we have accelerated our efforts, and we are fortunate to have a number of opportunities to explore.

Attempts to prepare an improved pertussis vaccine have a long history, spanning over 40 years. These past attempts have been impeded by technological limitations, but recently, science and technology have advanced--partially through the efforts of Public Health Service scientists--to enable the development of acellular vaccines. An acellular vaccine may contain one or more bacterial components which may be associated with protection from disease. The vaccines currently used in the United States are made from whole Bordetella pertussis bacterial cells.

Acellular pertussis vaccines have been in widespread use in Japan since 1981 and are reported to be associated with fewer, less serious adverse effects than current whole cell vaccines. We are not certain that the Japanese experience is directly translatable to our situation since the Japanese begin immunizing children against pertussis at two years of age, whereas we begin immunizing children with DTP vaccine at two months of age because early infancy is the time when pertussis poses the greatest danger to a child.

The published data from the Japanese concerning efficacy are limited and previous attempts by U.S. scientists to obtain information have been unsuccessful. I have recently written to the Japanese Minister of Health requesting permission to send a delegation of U.S. scientists to Japan to discuss in detail issues relating to acellular vaccine safety, efficacy, and testing.

CLINICAL TRIALS IN SWEDEN

Clinical efficacy trials can be best performed in countries with high pertussis incidence and well-developed laboratory services. Such trials are not practical in the United States because of the substantial success in controlling pertussis with whole cell vaccines. However, Sweden offers a unique opportunity for measuring the clinical efficacy of acellular vaccines.

Production problems led to a decrease in efficacy of the whole cell pertussis vaccine used in Sweden, and it was removed from the regular pediatric schedule in 1979. The incidence of pertussis disease rose and reached a peak of more than 1,200 cases in December 1982. After falling to a low of approximately 250 cases in April 1984, pertussis incidence began to rise again. The current incidence is expected to increase steadily through the fall of 1987.

The Swedish National Bacteriological Laboratory in Stockholm has been searching for an effective acellular pertussis vaccine. Early in their plans for a clinical trial, scientists from the United States and from the World Health Organization, realizing they had a rare opportunity to study the efficacy of acellular vaccines, began discussions with Swedish scientists about the trial design and financing.

The Swedish Laboratory has already chosen for the trial a product from the Biken Institute of Osaka University, Osaka, Japan, consisting of two components of the bacteria Bordetella pertussis. This acellular vaccine was safe and immunogenic in preliminary clinical studies in Sweden. A clinical efficacy trial of this vaccine is scheduled to begin in Stockholm, Sweden, in February 1986. It is anticipated that the trial will be completed by September 1987.

The Public Health Service has provided a significant portion of the funding for this trial and has expended considerable efforts to have another acellular vaccine considered for study. The two candidates currently under consideration for inclusion in the Stockholm trial contain pertussis toxoid only. One of the products is made by the Biken Institute and the other is made by the Michigan Department of Public Health. The latter toxoid vaccine is made under contract with the National Institutes of Health.

The Stockholm trial will provide information on the efficacy of at least one and possibly two acellular vaccines and will permit an evaluation of the more frequent types of adverse reactions. It will not be large enough, however, to evaluate serious, rare neurologic reactions.

An additional effort is being planned by scientists from the Laboratory of Developmental and Molecular Immunity of the National Institute of Child Health and Human Development. They are in the final stages of preparing a highly purified pertussis toxoid for initial tests in humans. Assuming the vaccine proves to be both safe and antigenic, a clinical efficacy trial may begin as early as 1986. This is a collaborative effort with the University of Goteborg in Sweden.

OTHER CLINICAL EFFORTS

The Committee on Vaccine Development of the British Medical Research Council has formed a subcommittee to plan an efficacy trial of new pertussis vaccines in the United Kingdom. Public Health Service officials have had discussions with them about possible candidate vaccines. The earliest starting date for such a trial would be mid to late 1986.

Other trials may be necessary to answer important questions concerning optimal vaccine composition, age at first vaccination, number of doses, and interval between doses. Efforts are presently under way to identify possible sites for such studies.

CONCLUSION

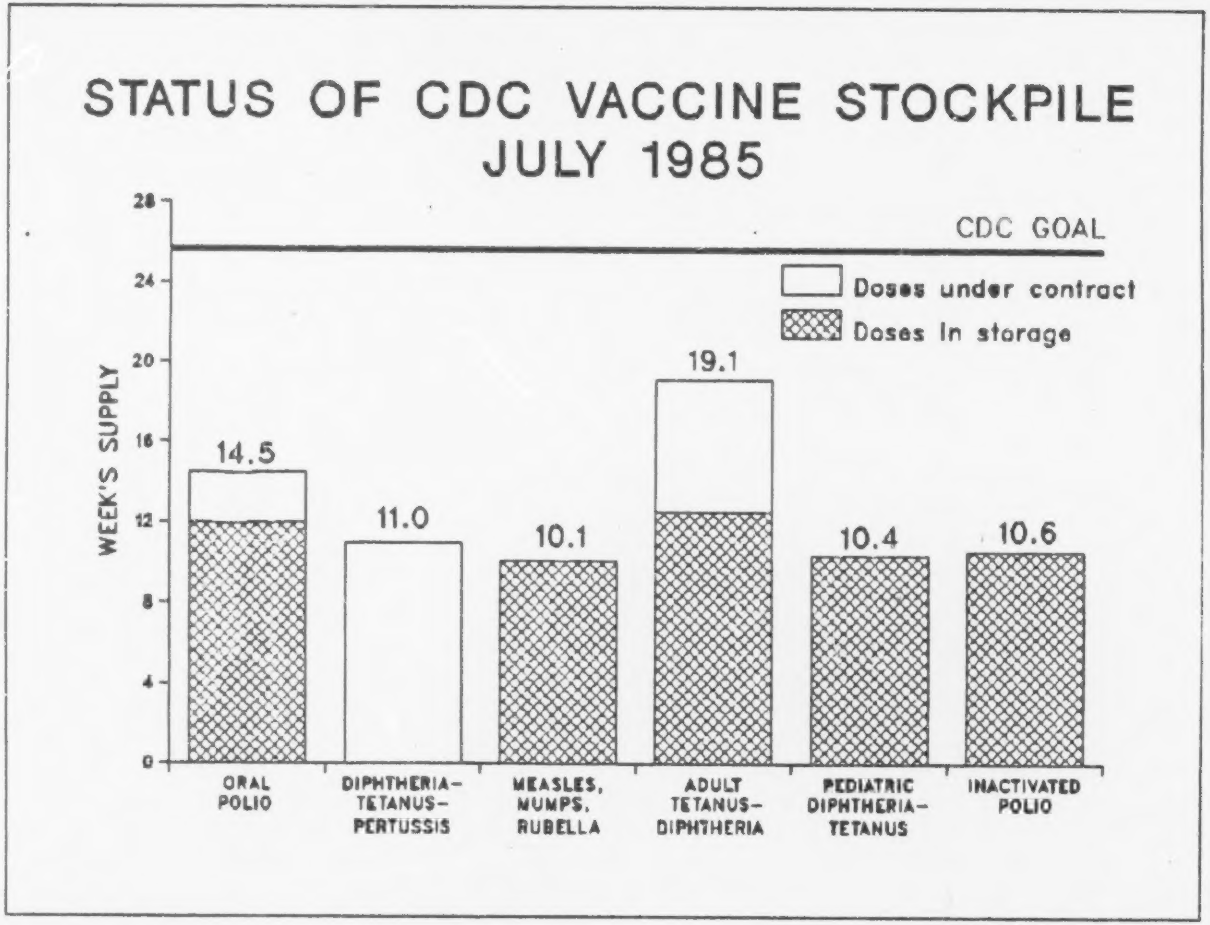
In summary, I have told you of the reduction in morbidity and mortality that has resulted from widespread use of vaccines to prevent childhood diseases in this country. We all agree that it is essential to assure a continued supply of these important products. We have recently weathered a crisis in DTP vaccine supply. However, the root causes that precipitated this crisis still exist. In addition, the other vaccines used to immunize children in the United States are currently supplied by single manufacturers, and these manufacturers also face liability exposure that may lead to difficulties in obtaining adequate levels of insurance.

The Administration's proposal would assure the continued supply of vaccines by minimally modifying the existing tort system. We would seek to eliminate punitive damages in vaccine-related injury cases and place a $100,000 cap on non-economic compensatory damages. There would be no limitation on the amount of economic loss compensation a plaintiff can receive.

At present, we do not have adequate information about current sources of compensation, and we believe action on any compensation proposal at this point would be premature. A proposed Advisory Commission should provide us with the needed information.

Finally, HHS has accelerated its efforts to support the development and testing of improved pertussis vaccines.

This concludes my prepared statement. I would be pleased to answer any questions you might have.


STATUS OF CDC VACCINE STOCKPILE
JULY 1985
CDC GOAL
Doses under contract
Doses In storage
WEEK'S SUPPLY
28
24
20
16
12
8
4
0
14.5
11.0
10.1
19.1
10.4
10.6
ORAL POLIO
DIPHTHERIA-TETANUS-PERTUSSIS
MEASLES, MUMPS, RUBELLA
ADULT TETANUS-DIPHTHERIA
PEDIATRIC DIPHTHERIA-TETANUS
INACTIVATED POLIO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

SEP 5 1985

The Honorable Orrin G. Hatch
Chairman
Committee on Labor and Human
  Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed are responses to the follow-up questions to the July 18 Committee hearing on childhood immunization.

Sincerely yours,

Lawrence J. DeNardis
Acting Assistant Secretary
  for Legislation

Enclosures

(1) Question: I know that there is an HHS-funded program of research in vaccine development. In view of the problem we are facing today, generated by doubts regarding the safety of the pertussis vaccine, would it be advisable to redirect funds from research into new vaccines to intensive research in developing, testing and getting to market a better pertussis vaccine?

Answer: We believe that shifting available vaccine research funds to an accelerated pertussis research program could retard future progress on research and development of other new vaccines such as those for the prevention of meningitis, hepatitis, bronchiolitis and pneumonia, and diarrhea in young children, which are also important areas.

Significant progress in developing vaccines against bacterial and viral diseases has resulted over the last decade from an increase in basic detailed epidemiological information, an increase in the world-wide research effort, recent advances in molecular biology, and an enhanced understanding of infant and childhood immunity. Much of this work has aided in the effort to develop a better pertussis vaccine. In the past five years, especially, there has been much activity in the pertussis field and many benchmarks have been achieved. Encouraging progress has been made in the development of acellular pertussis vaccines, and plans are being made for clinical trials for several such vaccines. We expect this progress to continue.

The development of any vaccine, especially pertussis, is a lengthy process requiring considerable patience and a coordinated effort at the national and international level. We are exploring ways to expand our efforts to develop an improved pertussis vaccine. It may be necessary and appropriate to reallocate resources, but preferably not at the expense of ongoing research on other new vaccines.

(2) Question: Do you have any evidence to suggest that the recent vaccine shortage was artificially induced or aggravated? (Senator Stafford)

Answer: The Cabinet Council Working Group on Vaccine Supply and Liability studied this issue. They found no evidence to suggest that the recent vaccine shortage was artificially induced or aggravated. The situation developed as follows: Connaught Laboratories, Inc., had difficulty in obtaining liability insurance and ceased distribution for a period. Wyeth Laboratories had previously withdrawn from the distribution of DTP. They subsequently made an arrangement with Lederle Laboratories, Inc., which provided for Lederle to distribute vaccine manufactured by Wyeth. Meanwhile, Lederle continued to manufacture vaccine as well. Some production lots which had been needed to maintain supplies failed to meet the requirements for release. These combined events led to the limited vaccine supplies.

Although there are currently two distributors for DTP, the root cause that led to the vaccine shortage--large and unpredictable court awards limiting availability of liability insurance to vaccine distributors--remains not only for the DTP vaccine but for the oral polio vaccine as well. We anticipate that the number of lawsuits filed against manufacturers will continue to increase and that those who insure vaccine manufacturers will continue to be concerned about the unpredictability and size of awards. The Administration proposal developed in coordination with the Working Group on Vaccine Supply and Liability seeks to provide a permanent solution to the vaccine supply and cost problems by dealing with the root cause.

(3) Question: Has HHS examined the alternative DTP vaccines for safety and effectiveness? If so, could you provide us with the results of those examinations? (Senator Stafford)

Answer: As you know, the DTP vaccine has three components: diphtheria, tetanus and pertussis. The component in question in terms of safety is the pertussis (whooping cough). HHS is studying alternative pertussis vaccines.

Acellular pertussis vaccines consisting primarily of two major pertussis proteins have been widely used in Japan for the past several years. HHS tried to obtain Japanese vaccine several years ago for clinical studies, but was unable to do so due to liability issues. The National Institute of Allergy and Infectious Diseases has offered the Institutes' contract supported vaccine evaluation units for studies on the safety and immunogenicity of any suitable candidate preparations developed by commercial manufacturers. Wyeth has used two of these centers to evaluate an acellular pertussis component they obtained in bulk from a Japanese manufacturer after the U.S. manufacturer agreed to assume liability for the product. The vaccine was compared to the conventional whole cell vaccine in 4 to 6-year, 18-month and 6-month old American children. The acellular component was associated with fewer minor reactions such as fever, fretfulness, pain, swelling and redness at the

(#3 continued)

site of injection. At the same time, the product maintained (i.e., the ability to produce antibody to specific pertussis antigens) when given as a booster immunization. Further tests of safety and antigenicity of this acellular vaccine in a primary series of immunizations at 2, 4 and 6 months of age are currently being carried out in one of the vaccine evaluation units. The infants in this study have been randomly assigned to receive either conventional pertussis or acellular pertussis vaccine in a double-blind fashion. The results of this trial are not yet available. If they confirm the findings of the earlier trial, the acellular vaccine may be considered as a candidate vaccine to demonstrate efficacy, i.e., protection from disease. The occurrence of rare, serious reactions can only be determined by surveillance implemented after a vaccine comes into general usage.

HHS expects to initiate clinical studies with a toxoid (single component) product prepared by the Michigan Department of Public Health in the fall and is also planning to support trials in Sweden with alternative pertussis vaccines. These trials are discussed in more detail in response to questions 6 and 16.

(4) Question: Does HHS now possess the expertise, or could it be acquired, to itself manufacture the DTP vaccine in the event of future shortages? (Senator Stafford)

Answer: This option was carefully considered by the Cabinet Council Working Group on Vaccine Supply and Liability. While HHS has the legal authority under section 352 of the Public Health Service Act to manufacture vaccines in short supply, it has no facilities or in-house expertise for doing so and therefore such an approach to dealing with shortage is out of the question as a short-term solution.

As the Working Group noted in its report, another possibility would be for HHS to purchase the vaccine from private manufacturers and then assume responsibility for its distribution throughout the United States. However, this would require the cooperation of the manufacturers; and under current law government purchase and distribution would not totally protect them from being sued directly. In order to protect manufacturers from direct suit, legislation such as that enacted for the Swine Flu program would be necessary.

(5) Question: If the United States government were to become the insurer of last resort for the drug companies, would you expect HHS to review the production practices, physician warnings, and other activities of the manufacturers in the same way that private insurers do? If so, would you expect to make information acquired by the government in this capacity available to the public? (Senator Stafford)

Answer: The Administration believes that the expertise necessary to provide appropriate insurance coverage for drug manufacturers is in the private sector, and it is totally opposed to the Government being forced by law to assume this responsibility for which it is inadequately equipped. Therefore, it is not appropriate to speculate as to the details of how the Government would administer such a program, which would require knowledge and experience that is currently concentrated in the private sector.

In regard to reviewing production practices, etc., HHS currently reviews production procedures and labeling. Information obtained by the Federal government is available to the public under the Freedom of Information Act, subject to the usual exemptions necessary to protect personally identifiable confidential information and proprietary data. However, we are unsure how private insurers do their review.

(6) Question: Can you tell us the present status of research for an improved DTP vaccine? How is this research being funded? Can you describe the involvement of the National Institute of Allergy and Infectious Diseases in this research effort? (Senator Weicker)

Answer: Recent advances in technology now allow for the production of acellular pertussis vaccines that have the potential for being as effective but safer than the current whole-cell vaccine. Several acellular vaccines have been developed in Japan and have been in general use in that country since 1981. Preliminary reports from Japan indicate that the vaccines are effective and relatively free of side effects. However, efficacy data and epidemiological data have been considered insufficient by many authorities. Before the Japanese technology is adopted for widespread use in the U.S., such data should be at hand. The Acting Assistant Secretary for Health has recently written to the Japanese Minister of Health requesting permission to send a delegation of U.S. scientists to Japan to discuss these issues.

The National Institute of Allergy and Infectious Diseases (NIAID) has offered to collaborate with any U.S. or foreign manufacturer in the safety and antigenicity testing of new acellular pertussis vaccines. HHS can not assume liability for products under test and this has prevented the Japanese companies from entering collaborative studies with the NIAID.

(#6 continued-page 2)

Wyeth, however, made arrangements to purchase Japanese-produced bulk pertussis vaccine which they combined with diphtheria and tetanus toxoids and packaged in the U.S. Wyeth has assumed liability for this product. It is under investigational study in U.S. children under the auspices of the NIAID vaccine evaluation units as well as in other centers.

With regard to what we know about other private sector initiatives, several manufacturers are working on their own version of acellular pertussis vaccines that contain immunizing antigens considered important in protection. Informal discussions with several manufacturers are being held regarding future testing of their products within NIAID-supported vaccine evaluation units. The FDA recently awarded a contract for the development and purification of pertussis antigens important in the disease process. These antigens will serve as an important research tool for laboratory studies and the standardization of serological assays.

The NIAID initiated an R&D contract in the fall of 1983 with the Michigan Department of Public Health, a licensed producer of biologics, to develop an acellular pertussis vaccine patterned after the Japanese product and composed of two major components. This work is proceeding ahead of schedule and at

(#6 continued-page 3)

least one vaccine is expected to be ready for clinical testing in children by this fall. In addition, investigators in NIAID's intramural research program are using recombinant DNA techniques in attempts to clone and express selected components from the pertussis bacteria. Testing of these "third generation" vaccines in the clinic is still several years away. Investigators at the National Institute of Child Health and Human Development (NICHD) have developed a vaccine composed of a single component--a toxoid pertussis vaccine--that they believe will confer immunity. A clinical efficacy trial is planned for 1986 in Goteborg, Sweden.

The Public Health Service Interagency Group to Monitor Vaccine Development, Production, and Usage, is also collaborating with Swedish scientists in Stockholm to design and conduct a double-blind, placebo-controlled clinical trial to evaluate the efficacy of Japanese acellular vaccines in six-to-twelve-month old children. Pertussis is now a common disease in Sweden because they stopped the routine vaccination of children several years ago. This study is important because it would examine the safety and efficacy of the Japanese vaccine in younger children. (The Japanese begin immunization against pertussis when children are two years old.) The Swedish trial

(# 6 continued-page 4)

will also examine the correlation between protection and serologic response. The efficacy trial is scheduled to begin in February 1986.

Research is underway in many parts of the world--including the United Kingdom, China, France, Italy, Switzerland and Japan--to develop new pertussis vaccines. Many of these efforts were reported at the Fourth International Symposium on Pertussis which was held in Geneva in 1984. This symposium is discussed in more detail in the response to question 16.

(7) Question: What is the Federal commitment of funds toward improved childhood vaccines? (Senator Weicker)

Answer: Funding levels for new and improved childhood vaccines -- acellular Pertussis, conjugated H. influenzae b, hepatitis A, hepatitis B (rDNA and synthetic), Varicella, Parainfluenza, Respiratory Syncytial virus Measles, Polio (IPV-OPV) and Rotavirus -- are estimated to be:

Childhood Vaccines

(Dollars in Millions)

	FY 1984 (Actual)	FY 1985 (Estimate)	FY 1986 (Estimate)
NIH	7.6	9.1	9.6 *
CDC	1.4	1.3	1.3
FDA	3.2	3.4	3.6
PHS, Total	12.2	13.8	14.3
Pertussis	(1.3)	(1.8)	(2.3)*

*Includes $750,000 contributed by USAID/OIH for pertussis clinical trial in Sweden.

(8) Question; If safe and effective childhood vaccines were this country's highest priority, how many dollars would be necessary to enable you to achieve that objective? (Senator Weicker)

Answer: The development and evaluation of new, improved vaccines is a major priority of both government and private sector groups; vaccine manufacturers commit substantial resources to this goal. Several PHS agencies, particularly NIH, CDC, and FDA, have major programs to support the development and evaluation of improved vaccines. The PHS commitment to this effort is detailed in the response to question 7.

The development of safe and effective childhood vaccines is a long-term effort which requires continued commitment of resources. In general, the amounts now devoted to this effort are adequate to achieve progress toward this objective. With respect to pertussis, the Department is currently considering resource requirements (both personnel and funds) necessary to accelerate the development and evaluation of improved pertussis vaccines.

In its review of priorities for vaccine development, the Institute of Medicine (IOM) examined a number of vaccines in various stages of development, including those considered high priority for immunization of children. ("New Vaccine

(#8 Continued)

Development: Establishing Priorities," Volume I, *Diseases of Importance to the United States*, (1985).) Listed below are the IOM's estimates of future costs and time to licensure for vaccines for eight serious diseases. The IOM's cost estimates include predicted expenditures by both public agencies and private industry, and assume Federal funds would provide support for basic research and early testing.

Pathogen	Vaccine Envisaged	Estimated Future Costs ($ in millions)	Time to Licensure (years)
Bordetella Pertussis	Acellular	$10	3-5
Hemophilis influenza type b	Conjugated polysaccharide	30	3
Hepatitis A	Attenuated live virus	15	4
	Subunit	25	5
Hepatitis B	rDNA	10	1-2
Varicella	Attenuated live virus	5	2
Parainfluenza	Trivalent, subunit	25	5
Respiratory syncytial virus	rDNA	25	5
	Attenuated live virus	25	5
Rotavirus	Attenuated bovine	10	2-3
	Attenuated human	20	2-4

(9) Question: What incentives are we providing to industry, particularly those who produce biosynthetic products, that will augment the efforts in vaccine production? What can this Committee do to improve these incentives? (Senator Weicker)

Answer: The HHS agencies have provided incentives in various forms which are applicable to vaccines made by any technique:

- Support of basic research through grants, contracts and intramural research;
- Consultation and discussion as to the types of antigens and cell substrates which might be suitable in new vaccines;
- Assistance in laboratory analysis;
- Written guidance to manufacturers in the areas of the new technologies--recombinant DNA and hybridoma technologies;
- Workshops and meetings to disseminate information on various aspects of production regulation and use of different products;
- Use of the NIAID vaccine evaluation units for clinical testing of candidate vaccines.

In situations where there are single manufacturers for a product, one incentive to develop an improved product--that of commercial competition--is missing. The primary reason for single manufacturers, at least for oral polio and in the recent past for DTP, has been the liability situation. The Committee could improve incentives by enacting legislation that deals with the root cause of this problem. We believe that the Administration's proposal to eliminate punitive damages in vaccine-related injury lawsuits and cap non-economic damages at $100,000 would be a major step toward correcting the liability situation.

(10) Question: Do you think the Federal government needs to invest more in research on safer vaccines? (Senator Kennedy)

Answer: Research on improved vaccines is an effort which occupies many Federal, university, and industry scientists. In general, the amounts now devoted to this effort are adequate. As pointed out in the answer to question 8, the Department is currently considering resource requirements necessary to accelerate the ongoing development and evaluation of improved pertussis vaccines.

(11) Question: I understand that estimates of the number of vaccine injuries and the circumstances under which they occur are highly problematic because of the lack of a mandatory and systematic surveillance system. S. 827 proposes a way to address this. Do you object to the establishment of a system such as provided in S. 827? (Senator Kennedy and Senator Hatch).

Do you agree that there is serious under-reporting of injuries? How could we most reasonably and feasibly deal with this? (Senator Hatch)

Answer: The Administration would object to the proposed mandatory system of reporting as detailed in S. 827. That proposed system would simply place paperwork burdens on physicians without materially adding useful information. S. 827 would require reporting of a broad range of reactions, including high-pitched unusual screaming and persistent uncontrollable crying. Physicians would have to report these events whenever advised of their having occurred, whether or not the events were medically or otherwise corroborated. Hence, reporting would be highly unreliable and of little use in making judgments regarding causation. Moreover, these uncorroborated reports would become part of the patient's medical record, thereby raising the potential for inappropriate medical care and unwarranted compensation claims.

(#11 continued-page 2)

Many of the problems regarding estimates of the numbers of vaccine injuries and the circumstances under which they occur are not due to underreporting as much as they are due to the substantial technical difficulties in determining whether events temporally related to the administration of vaccines are actually caused by the vaccines. Determination of causation, particularly for rare events, usually requires difficult to perform, extensive studies in which rates of adverse events following vaccine administration are compared with rates of such events in the absence of vaccines.

We agree that there is underreporting of adverse events following vaccination. The Food and Drug Administration is considering the development of regulations that would make reporting of adverse reactions to biologics mandatory for manufacturers. Such reporting is currently required for drugs, and we believe that it may be appropriate for biologics as well.

In regard to mandatory reporting of adverse reactions by those who administer the vaccines, HHS currently requires reporting to CDC of adverse events that require medical attention and occur within four weeks following receipt of Federally provided vaccines. This system, which has recently been improved, provides a good indicator of the spectrum of events following administration of 40 to 50 percent of all childhood vaccines. We do not believe that required reporting by private physicians as contained in S. 827 would materially improve the situation. We would support a demonstration study of improved methods for the voluntary reporting by physicians of adverse reactions associated with the administration of vaccines or other biologics.

(12) Question: In testimony at previous hearing, and in conversation with victims, I and my staff have been informed that some vaccine injuries could have been avoided if providers and parents had been aware of contraindications to vaccine administration. S. 827 includes provisions to improve public and provider awareness of instances in which administration of vaccine would not be good medical practice. Could you comment on those provisions of the bill? (Senator Kennedy)

Answer: Although both providers and parents should be aware of the potential contraindications to vaccines, even careful attendance to contraindications will not totally eliminate adverse events. We believe that providers already have substantial access to such information in recommendations of advisory committees such as the Committee on Infectious Diseases of the American Academy of Pediatrics and the Immunization Practices Advisory Committee of the Public Health Service, and in the package inserts which accompany all vials of vaccine.

Parents whose children are to be vaccinated in the public sector are informed about contraindications by a series of Important Information Statements which have been developed by the Centers for Disease Control. Parents or guardians of

(#12 continued)

children receiving vaccine in the public sector must read and sign these forms before vaccines are administered. These forms contain in concise language, the key information on benefits of vaccine, risks of vaccine and contraindications. The forms have been reproduced for private physicians in publications of the American Academy of Pediatrics. Greater use of these statements in the private sector would be helpful.

Provisions of S. 827 regarding transmission of adverse-event and contraindication information to parents are unduly burdensome and written in a biased manner with excessive emphasis on adverse events. This section of the bill, as written, has great potential for undoing much of the progress that has been made in controlling disease through vaccination.

(13) Question: S. 827 includes beefed-up record-keeping requirements for vaccine manufacturers, including reports on significant problems with any batch, and complete reports of safety testing of each batch of vaccine. Would you comment on the desirability of those requirements? (Senator Kennedy)

Answer: The Administration opposes S. 827, including those provisions relating to manufacturers' record keeping, because they add nothing to FDA's authority under existing law and much of what is called for by S. 827 is already provided to FDA in protocols submitted for each vaccine lot prior to release for distribution.

Moreover, the requirement in S. 827 that each safety test be reported within 30 days is undesirable, since it has the potential for information to be submitted in a piecemeal fashion and in no useful context.

(14) Question: Tell us about any recalls of "bad batches" of DPT vaccine over the last 10 years. How many recalls have there been? How much vaccine has been pulled off the market? (Senator Metzenbaum)

Answer: Since 1975 there have been three recalls of DTP vaccine: All were voluntary manufacturer recalls.

1977 - Parke Davis recalled one lot due to incorrect dating period: 3015 vials.

1978 - Sclavo Inc. recalled three lots due to an increased incidence of sterile abscesses. This involved 27,203 vials, 27,647 vials, and 18,227 vials, respectively. (Each vial contained 15 doses.)

1984 - Massachusetts Department of Public Health (D.P.H.) recalled the affected portion of a lot due to the presence of rubber particles. The unaffected vials remained on the market in the areas served by the Massachusetts D.P.H.

(15) Question: Is the current DPT vaccine on the market today the safest such vaccine that science can produce? (Pursuant to this quote, from the 1982 HHS symposium on pertussis vaccines, by Dr. Cameron: "... Sure you can produce a much less toxic product in very low yields, and anyone who has worked on pertussis knows this.") (Senator Metzenbaum)

Answer: DTP vaccines containing a whole cell pertussis vaccine component have been determined to be safe and effective considered in the light of risks of the disease. It is the goal of a great deal of current effort to produce a safer and equally effective or more effective product. These efforts are directed toward using purified components (including detoxified toxins), isolated from Bordetella pertussis which could be substituted for whole cell pertussis vaccines. Such vaccines have the prospect to be safer than whole cell pertussis vaccines, but there is presently only limited evidence that such vaccines would be clinically effective. Until a candidate vaccine has been shown to be both clinically safe and clinically effective, it can not be approved and recommended for routine clinical use.

The quote from the 1982 DHHS Workshop on Pertussis Vaccines, attributed to Dr. Cameron, as far as we can determine, was actually made by Dr. Stainer (page 11-30, lines 10-12). No scientist, then or now, has any special knowledge of how to make a much less toxic pertussis vaccine that is as effective as the current vaccines. Drs. Stainer and Cameron were referring to a hypothetical situation in which an expensive, safe and effective vaccine would be available to those nations that could afford it, and that a less safe and possibly less effective vaccine would be available to poorer nations. The financial, ethical, and logistical issues here are quite obvious, and Drs. Cameron and Stainer were bringing this to the attention of the Workshop's participants.

(16) Question: (A) What has HHS done in the last four years to develop a safer pertussis vaccine? (B) Are you satisfied with the potency labeling and warnings which accompany the DPT vaccine? (Senator Metzenbaum)

Answer (A): The laboratory and clinical studies done on a safer pertussis vaccine in the last four years have been built on a program of research and development in HHS that has been underway for many years. Several HHS agencies have played major roles in supporting and/or conducting research on pertussis and pertussis vaccine.

- The National Institute of Allergy and Infectious Diseases (NIAID) has maintained an active and productive program for many years at their Rocky Mountain Laboratories, which has been engaged in basic studies of Bordetella pertussis, the bacterium that causes whooping cough. More recently, the staff of the Rocky Mountain Laboratories has been expanded to include research on the genetics of B. pertussis. The NIAID has provided grant support for research done in university laboratories and is supporting research under a contract with the Michigan Department of Public Health to develop an acellular pertussis vaccine. Facilities for clinical trials to evaluate new pertussis vaccines are supported by NIAID contracts with several universities, and a contract will provide a major source

(#16A continued-page 2)

of funding for the Swedish clinical trials with acellular pertussis vaccine.

- A National Institute for Child Health and Human Development intramural laboratory has developed an acellular pertussis vaccine composed of a single component, called a toxoid. Clinical trial on this product are planned for 1986.

- The Center for Infectious Diseases and the Center for Prevention Services of CDC has several laboratories and programs engaged in research to improve the diagnosis of pertussis and study the epidemiology of the disease. These studies provide information which can be applied to the study and use of new vaccines. At the present time, the CDC supports contracts for extramural research to improve the laboratory diagnosis of pertussis and to examine alternative immunization schedules with pertussis vaccines.

- The Food and Drug Administration (FDA) funded a contract to study the genetics and physiology of B. pertussis, a contract to evaluate the adverse reactions associated with the use of pertussis vaccine, and a contract to develop and produce antigens which can be used as reagents and as prototype vaccine components. FDA's Pertussis Laboratory has been engaged in research on pertussis and pertussis vaccine for many years, and has been recognized for their contributions by being designated as the World Health Organization Collaborating Center for Research on Pertussis Vaccines. This laboratory has developed procedures for purifying several pertussis antigens including lymphocytosis promoting factor (LPF), filamentous hemagglutinin (FHA) and two agglutinogens. It has developed animal models for evaluating the capacity of these antigens and their antibodies to prevent experimental disease. Methods by which LPF may be detoxified are being evaluated. It also developed serological assays which appear useful for diagnosis as well as for evaluating the immune responses to different kinds of vaccines.

- The PHS Interagency Group to Monitor Vaccine Development, Production, and Usage, which includes representatives from NIH, CDC, and FDA, has been meeting with representatives from the Swedish National Bacteriology

Laboratory for the past nine months to help coordinate, plan, and discuss possible financing of a proposed U.S./Swedish collaborative study on the efficacy of a precipitated- purified acellular pertussis vaccine made in Japan. The purpose of the study is to reintroduce general pertussis immunization for children in Sweden as soon as possible, and to determine the percent reduction in disease due to pertussis among recipients of the new acellular Japanese vaccines compared to control children of the same age groups who will receive a placebo. The study will also attempt to evaluate the correlation between protection and protective antibody responses and assess the incidence of adverse reactions with the new vaccines. The efficacy trial represents the first controlled trial an acellular vaccine of the type developed in Japan and is scheduled to begin in February.

- The Public Health Service has sponsored several meetings on pertussis research. In 1978, the Third International Symposium on Pertussis was organized by Food and Drug Administration scientists in collaboration with the National Institutes of Health, Centers for Disease Control, and the International Association of Biological Standardization. The meeting was held in Bethesda at the

National Institutes of Health. The proceedings of the that symposium have been published (Manclark, C.R., Hill, J.C. Eds. 1979. International Symposium on Pertussis. U.S. Government Printing Office, Washington, D.C.).

In 1984, the Fourth International Symposium on Pertussis was organized by Food and Drug Administration scientists in collaboration with the International Association of Biological Standardization and the World Health Organization. This meeting was held in Geneva. The proceedings of this symposium (Manclark, C.R., Hennessen, W. Eds. 1985. Proceedings of the Fourth International Symposium on Pertussis. S. Karger, Basel, Munchen, New York) are in press and should be available in late 1985.

A workshop entitled "New Pertussis Vaccines-Laboratory and Clinic Evaluation," sponsored by the FDA, NIH, and CDC was held in 1982 to consider the possible formulations for the new acellular pertussis vaccines and determine the best methods for the evaluation of the clinical safety and efficacy of candidate vaccines.

In addition to serving as a forum for the reporting and discusion of pertussis vaccine research, the workshop and the symposia developed a consensus of the current state of our knowledge and proposed avenues of research. These meetings are considered by most investigators to be major milestones in moving pertussis vaccine research forward.

Answer (16B): The labeling of DTP Adsorbed and Pertussis Vaccine Adsorbed contains an estimate of potency of the pertussis vaccine component based on a statistical evaluation of the bioassay results. The variation around the estimate of 12 units per total human dose is related to the nature of the bioassay employed. All regulations are periodically reviewed by FDA and an evaluation of the variability of the bioassay used to assess pertussis vaccine potency is underway at this time.

Warnings and related information material contained in the labeling for DTP Adsorbed and Pertussis Vaccine Adsorbed are based on facts developed by the scientific and medical communities and determined to be significant by the FDA Vaccine Review Committee, the Immunization Practices Advisory Committee and the American Academy of Pediatric's Committee on Infectious Diseases. At times, manufacturers have included more stringent warning than those cited by these advisory bodies. Labeling is reviewed periodically and approved by the FDA. Either the FDA or the manufacturer may initiate a labeling review.

(17) Question: What practical and scientific obstacles need to be overcome to develop safer and improved vaccines, particularly the pertussis vaccine. Please give details where possible and explain the reasoning behind your answer. (Senator Kerry)

Answer: The Institute of Medicine addressed the problems related to vaccine manufacture, innovation and priorities in two major reports issued this year:

- New Vaccine Development: Establishing Priorities
  This study was funded by the National Institute of Allergy and Infectious Diseases.

- Vaccine Supply and Innovation
  This study was funded by the Food and Drug Administration, the Centers for Disease Control, the Department of the Army, grants from manufacturers, and special funds available to the National Research Council.

In brief, the major practical and scientific obstacles are (1) the high cost and logistics of conducting clinical trials to determine efficacy and (2) the availability of scientific opportunity that can be exploited to develop improved vaccines.

(#17 continued-page 2)

In regard to the first obstacle, unless there is a scientific breakthrough which will permit the evaluation of safety and efficacy by some other means, clinical trials to evaluate efficacy will require a considerable expenditure of effort and resources and may require several years to complete. In the case of pertussis, the high cost of clinical studies is further complicated by international arrangements that have to be made to test for efficacy. Because of the substantial success in controlling the disease in the United States, efficacy tests of the pertussis vaccine will have to be conducted elsewhere. We have discussed in response to questions 6 and 16 our efforts with Swedish health authorities. We are in the process of negotiating with other countries to conduct trials as well.

Producing a new vaccine is greatly dependent upon scientific opportunity. For this very reason, the pertussis vaccines have not changed since their first formulation. As a result of research, much of it in government laboratories or funded by government monies, the host parasite interactions in pertussis and the immunochemistry of the pertussis bacteria are being elucidated. Scientists have identified candidate vaccine components, methods for detoxification of toxins, and laboratory models for study of these components. All these scientific underpinnings were necessary before clinical trials could be performed.

(#17 continued-page 3)

Although there is great interest in clinical trials of the pertussis vaccine to establish safety and efficacy, it is clear that laboratory research must continue. Once the immunogens have been identified, studies to produce them by classical methods, genetic engineering, or synthesis will be necessary. The manner in which a vaccine is used is as important as the vaccine itself. There is a need to examine the time and age or immunization so as to reduce risk, optimize immunity in susceptible individuals, prevent infection, and protect those at greatest risk.

To have committed large amounts of money and personnel to the development of an improved pertussis vaccine in the past would have been less productive because the science and information were not available. Today the prospect for some success in the clinic exists because the science necessary to expand laboratory studies is in place.

(18) Question: S. 827 mandates an affirmative duty of the Federal government to encourage development of safer vaccines. In view of the importance of vaccines for public health, and the efforts in this area which Dr. Mason's testimony described, do you have any objection to establishing this statutory mandate? (Senator Kennedy)

Answer: The development of vaccines is a complex process which cannot be expected to follow rigid legislative schedules. The Administration strongly opposes provisions in S. 827 that would nevertheless attempt to mandate such schedules and then would put the Government in the untenable position of being subject to "citizen suits" if scientists are unable to adhere to these timetables.

(19) Question: The parents' group contends that the tests which are currently performed on each batch of vaccine are useless for the purpose of assuring the safety of the batch. Do you concur with this assessment? Are better tests available? (Senator Kennedy)

Answer: The ideal control test for vaccine toxicity should be a direct measure of the toxic component. The test should be technically feasible and reproducible within and between laboratories and the results of the test should be a direct measure or correlate with clinical experience with the vaccine. Our knowledge of the vaccine components responsible for toxicity is incomplete, and although attempts have been made to relate various virulence factors of Bordetella pertussis to vaccine reactions, these attempts have been unsuccessful for the most part. Assays that have been suggested to replace existing tests of vaccine toxicity lack reproducibility or have not been correlated with clinical reaction rates.

The current mouse toxicity test provides an overall assessment of vaccine freedom from toxicity. Specific assays are available for each of these toxins, and although FDA does test some lots of pertussis vaccines for these toxins, the assays are considered to be experimental and not suitable for product control at this time. Some of these assays are presently in use for the control testing of whole cell vaccines in other countries. HHS scientists are unaware of a body of published evidence that relates the results obtained with any laboratory assay to the ability of a vaccine to induce severe neurological reactions in children.

(20) Question: We all know that the process of suing to recover damages in the court system is a lengthy and expensive one. To the degree that some vaccine injuries are indeed unavoidable, what is wrong with a simpler, less costly, no-fault approach? (Senator Kennedy).

Answer: The Administration believes that its proposal to ban punitive damages and to cap non-economic damages will remove existing disincentives to reasonable and expeditious settlements under the traditional tort system. The Administration opposes the compensation system set forth in S. 827 since, in attempting to provide maximum compensation to anyone who may conceivably have been harmed by a covered vaccine, it adopts an approach that is likely to provide compensation to many whose injuries were not caused by vaccination. As the result, the system will probably be very costly and inequitable. At the same time, since individuals may choose to pursue current tort remedies, it will not necessarily alleviate the liability problems faced by vaccine manufacturers.

The Administration has on previous occasions outlined in some detail its concerns about S. 827 and its predecessors in the previous Congress. Despite some changes from earlier versions, S. 827 still allows claimants to prove injury and causation based on very little evidence. In addition, since compensation decisions are to be made in non-adversarial ex parte proceedings

(#20 Continued)

in federal court, no party responsible for overall operation of the system is permitted to challenge the claimant's evidence and assertions. While some provision is made for financing through surcharges, in the end much of the cost is likely to have to be borne by the Treasury, with no projections that are any more reliable than those previously made for the Social Security disability, Medicare/Medicaid, and Black Lung programs. Without going into further details, the bill is a poor solution to a problem that is best left to the tort system as modified along lines suggested by the Administration.

(21) Question: How long has HHS been examining the issue of vaccine compensation? How many recommendations has it formally made on the issue? Have you involved parents of vaccine-damaged children in your deliberations? (Senator Metzenbaum)

Answer: The Department has been involved in the study of the vaccine liability-compensation subject since 1973. Several studies have been conducted and reviewed since that time. In addition, the Department has studied in detail a number of proposals, including those of the American Academy of Pediatrics, the American Medical Association, the Congressional Office of Technology Assessment, Senator Hawkins, Congressman Waxman, and Congressman Madigan. The development of many of these proposals involved parents of vaccine-damaged children.

On July 1, 1985, the Working Group on Vaccine Supply and Liability of the Cabinet Council on Human Resources, after reviewing the proposals mentioned above, recommended enactment of legislation to ban punitive damages in vaccine-related cases and to place a cap on non-economic damages. This recommendation served as the basis for the Administration proposal. The Working Group also proposed establishment of an Advisory Commission on Childhood Vaccines to review the compensation policies under current law and the adequacy of compensation for vaccine-related injuries.

(22) Question: In view of the potential for interruption of the vaccine supply, would it not be prudent to complete the vaccine stockpile this year? When do you think it should be completed? (Senator Kennedy)

Answer: The stockpile initiative was begun in 1983 to build an emergency supply of vaccine in case the limited number of domestic vaccine manufacturers stopped production. Another $4 million are requested again in the FY 1986 President's Budget (on top of the $12.5 million provided since 1983) to continue its development. Depending on the rate of future price increases in the cost of vaccines, we would expect to complete the stockpile in the next few years.

The stockpile was designed as a multi-year project primarily because of limited production capacity. Too rapid a build-up would have required manufacturers to suddenly increase their production and then gear down. Such an approach was judged to be uneconomical. Given that much of the stockpile that remains to be purchased is for DTP vaccines, it would be particularly difficult to complete the stockpile in 1986 because of some continuing production and distribution problems. Currently DTP vaccine supply is barely meeting demand and we project that DTP will not actually begin to be placed in storage until January 1986. It is therefore doubtful that the full vaccine stockpile of DTP vaccine (10.5 million doses) could be completed in one

(#22 Continued)

year, 1986, due to lack of availability of vaccine. The following table indicates the stockpiled vaccines purchased to date and the amount needed to complete the 6-month stockpile:

(Doses in millions)

Vaccine	# Doses Purchased to Date FY 1983-1985 ($12.5 mil.)	Add. Doses Est. to be Purchased in FY 1986 (+$4 mil.)	# Doses Remaining to be Purchased	#Doses Projected Total Vaccine Stockpile
OPV	5.716	1.122	1.562	8.400
MMR	0.992	0.175	0.933	2.100
DTP	3.960	1.297	5.243	10.500
Td (adult)	3.500	0.500	1.700	5.700
DT (pediatric)	0.200	0.100	0.200	0.500
IPV	0.019	0.010	0.001	0.030
TOTAL	14.387	3.204	9.639	27.230

(23) Question: Do you have any objection in principle to the Federal government having an insurance or re-insurance authority in reserve in the event it is necessary to assure a continued vaccine supply? Why" How would such authority be harmful, even if it never needed to be used?
(Senator Kennedy)

Answer: Yes, we would object in principle to giving the Federal Government insurance or re-insurance authority even on a standby basis. We believe that the current system of private vaccine production and private insurance has worked well in the past and, with the minor adjustments recommended in the Administration's proposal, could continue to work well. The passage of standby authority would encourage eventual use and the result will likely be very costly to consumers and taxpayers. If Federal insurance or re-insurance authority is necessary, such as in a situation where there were no private sources of pertussis vaccine, such authority could be developed and implemented with enough lead time to prevent threatening the current level of protection against pertussis in the United States.

(24) Question: If you have not already done so in previous questions, please comment on the information and reporting requirements of S. 827 (especially sections 2141, 2143, and 2145). (Senator Kerry)

Answer: See answers to questions 11, 12, and 13.

(25) Question: I guess the bottom line question with respect to safer vaccines is when do we expect to be able to have a safer vaccine on the market? The answer to this question has some implications for our action on the compensation bills which are now before the Congress. Can you speak to this question of when we will have a safer vaccine? (Senator Grassley)

Answer: Candidate vaccines are being evaluated now in the laboratory and in humans. As discussed in the response to question 17, it is projected that clinical evaluation of safety and efficacy will require at least three to five years. These studies include those planned in Sweden. Problems associated with the manufacturing of the new vaccine in quantities to meet the country's needs would be expected to be addressed within the same period of time. It should be realized, however, that despite scientists' best efforts there are no guarantees in research. If progress is slowed by unexpected developments, or if the new vaccines prove not to be effective as hoped, additional years of effort might need to be expended. After demonstration of safety and efficacy and the licensing and use of the new vaccines, post-marketing studies will be needed to determine the duration of vaccine immunity and the incidence of rare adverse effects. No vaccine can be expected to be completely free of side effects, and it should be recognized that coincidental events will continue to occur. Thus, liability and compensation problems, although lessened, will remain with any new products.

Senator HAWKINS. Thank you. Could you tell me the amount of money the Federal Government now pays for MMR vaccine?

Dr. MASON. Alan, could you supply that?

Dr. HINMAN. Our present price for MMR vaccine is about $6.80 a dose.

Senator HAWKINS. Six?

Dr. HINMAN. $6.80 a dose, roughly.

Senator HAWKINS. $6.80 for MMR. So that's gone up from $5.16 a dose since 1983?

Dr. HINMAN. Yes, ma'am.

Senator HAWKINS. And the private physician pays $14.88?

Dr. HINMAN. Roughly.

Senator HAWKINS. Roughly. So let me verify my numbers. DTP vaccine has increased from $2.80 a dose to $4.29 a dose.

Dr. HINMAN. That is the recent announcement by Lederle. Our contract with Connaught is at $2.21 a dose, and that contract extends until April next year.

Senator HAWKINS. Until when?

Dr. HINMAN. April of next year.

Senator HAWKINS. April of 1986?

Dr. HINMAN. Yes, ma'am.

Senator HAWKINS. But for others who do not buy from the Government, the announced price increase was from $2.80 to $4.29?

Dr. HINMAN. Yes, ma'am. I do not know what Connaught's price in the private sector is at the present time.

Senator HAWKINS. Well, 15 million doses of DTP given a year, that is a $22 million increase, projected increase, on DTP. The cost of polio vaccine has risen from $2.80 a dose in 1983 to $6.23; is that correct?

Dr. HINMAN. That is what Lederle has recently announced.

Senator HAWKINS. Today. So with 8 million doses of polio vaccine administered each year, that's another $26 million increase since 1983.

Dr. HINMAN. Your arithmetic is ahead of mine, Madame Chairman. Our price in the public sector is currently eighty cents a dose.

Senator HAWKINS. How much?

Dr. HINMAN. Eighty cents a dose.

Senator HAWKINS. And the MMR's we discussed in 1983 was $5.16, and you state that it is now $6.80, and a physician pays approximately $14.88.

Dr. Mason, have any safeguards been put in place by the administration to prevent another disruption of vaccine supply?

Dr. MASON. There are a number of activities that have been put in place, and of course one of those is the vaccine stockpile which would enable us to weather, at least, temporarily, a storm.

Of course, we are also working closely with vaccine manufacturers, and we feel that the administration's proposal would provide a source of insurance that would encourage vaccine manufacturers to stay in the marketplace, which is the most worrisome problem that we are encountering at this time.

Senator HAWKINS. Way back in 1982, I introduced a bill, S. 2950, which called for the study of each issue that's specified in your commission. That study, which was conducted by the Interagency Task Force on Vaccine Production, Development and Usage, was the subject of our pertussis task force hearing which was held 2 years ago.

At that time you provided me with the summary and reference to documents that indicated that this issue, both vaccine supply and compensation for vaccine injury, had been studied by your Department since at least 1976. Is that correct.

Dr. **Mason**. I believe that is correct, Madame Chairman.

Senator **Hawkins**. This document also makes reference to a congressionally mandated national immunization work group, including a working group on liability that issued its report and recommendations to Congress in 1977. The Office of Technology Assessment published two reports on this subject in 1979 and 1980, and one was entitled "Compensation for Vaccine-Related Injuries."

So you must have been considering these reports and recommendations—back in 1981, the National Center for Health Services Research commissioned a study on the estimated economic cost of selected medical events known or suspected to be related to the administration of vaccine. So we are talking about 1976, 1977, 1979, 1980, 1981—don't you think there have been enough studies and enough commissions on this issue? Isn't this new commission you are telling me about and this new study just another delaying mechanism, designed to soften the impact of the rest of the bill?

Dr. **Mason**. That's not the purpose at all. There have been a number of studies over the years. Each of these studies has not recommended any particular system. They have not reached a consensus, and one of the problems has been getting definitive information which would provide us with data. That's why the advisory commission incorporated into the administration's proposal would provide for subpoena power so that we could get the very records and the data that are necessary to establish the facts.

Senator **Hawkins**. I feel that the message we are giving to parents is that we're concerned, and we are going to study it one more time; and it seems to me that this bill before us today is simple, straightforward; and as a result of the enactment of this legislation, you would have a lot more accurate data at the end of the year than you are going to have by commissioning another study, which is voluminous. And, at the same time, if you do nothing, the cost of the vaccine increases so dramatically until it's being priced at a great cost to the taxpayer, whether we reimburse those that have adverse reactions or not.

Dr. **Mason**. Eliminating punitive damages and putting a cap on pain and suffering would have a greatly modifying effect upon the cost of vaccine, as related to liability insurance.

Senator **Hawkins**. I know that's your position. That's not the position of S. 827, and I feel that we are on the right track and we may be able to pass that this year, and you won't have to do the study. We want to save you the paper work.

Dr. Hinman, may I ask—the Japanese data, I'm told, can't be used because they administer the vaccine to much older children in Japan, while we give it to very small infants.

Why do the Japanese give it to older children?

Dr. **Hinman**. I believe the rationale was that when the original event occurred in 1974, and what precipitated the change in immunization policies in Japan, as I understand it, was the occurrence of two deaths in children who had received DTP vaccine within the preceding 24 hours.

At that time, the Japanese Ministry of Health recommended the suspension of the use of DTP vaccine while the subject was being investigated. Subsequently, it was determined, or was felt, that these deaths were not related to DTP vaccine; and in April of that year, 3 months later, a recommendation was made to continue using DTP vaccine, but on the thought that perhaps reactions might be age-related, the vaccine was administered at 2 years of age. That policy has continued to the present.

A new vaccine was developed and put into use in 1981, the acellular vaccine, and that is still administered at 2 years of age rather than 2 months.

Senator HAWKINS. Dr. Mason, will the administration request more funds to cover the price increases that we have discussed today?

Dr. MASON. Secretary Heckler has asked us to make her aware of those increases so that that can be reflected in our budget submissions.

Senator HAWKINS. What if Congress freezes funds?

Dr. MASON. We're going to have problems. We will either have to cut down on services rendered at the State and local levels to make sure that the vaccines are given to children, or we will have to reduce the number of vaccine doses available.

Senator HAWKINS. If we reduce the number of doses, will we have an outbreak?

Dr. MASON. That's a worry; a reason to be concerned about the price increase. It isn't enough to just have vaccine available. There has to be the organization and the personnel to administer those vaccines. Both sides of that equation have to be there if we are going to maintain immunization levels that have resulted in the dramatic decrease in cases, deaths and disability.

Senator HAWKINS. I'm pleased with your news on the stockpile; but if you recall, CDC didn't want the funds. Congress forced them to take it, and we're pleased that you used it wisely.

Mr. Willmore, we would like to hear from you at this point, if you would summarize your statement.

Senator DODD. Madame Chairman, could I——

Senator HAWKINS. Oh, excuse me. I missed you, Senator Dodd.

Senator DODD. The questions will probably be the same for all of them, but I was somewhat taken aback, I suppose, by what seems to be the administration looking at only one side of this particular problem: identify the problem of the manufacturer.

It's very legitimate, but in the process, it seems to me that you've totally neglected to really focus attention on the injured parties, and this whole related area. You, at least in passing, left me with the impression that you felt the no-fault system was a mistake across the board. What immediately came to mind, of course, was home insurance, health insurance, unemployment compensation and a variety of other systems that have been not only efficient, but have provided compensation for injured parties and reduced costs substantially.

I don't know if you are familiar with the no-fault insurance law in the State of Michigan, for instance, where they have provided for compensation for unlimited medical expenses, rehabilitation costs, and up to $50,000 for work loss. That program, at least up to now, has reduced costs by more than 50 percent of what the costs were under the previous tort system in that State, and provided, as I mentioned, adequate compensation for people who are injured, which is missing in your presentation here this morning.

My concern, and I would pose this in a question to you and Mr. Willmore who can comment now or after he testifies, but it seems to me that the Government just caps awards, and the courts continue to expand the theories of recovery. We remain silent on that, which could lead the courts to conclude that we basically agree with what they are doing. The result, it seems to me, could be compensation for all victims for economic losses, plus a multiple for noneconomic losses, plus the transaction costs, attorneys and so forth, raising the particular dollar amounts.

I wonder if you wouldn't comment on whether or not it wouldn't be better to agree on relevant symptoms that we are talking about here that would entitle injured parties to compensation through a system, without having attorneys, and only permit those suits where the manufacturer was really negligent. Doesn't that seem to make more sense than trying to deal with both sides of this particular problem: the problem of the manufacturer and the problem of the injured party, seeing to it that they receive adequate compensation, get it soon, and don't have the great disparity that we have seen between bona fide claimants that the tort system has been producing over and over again for the past number of years?

Dr. Mason. I believe that Mr. Willmore is going to include that in his testimony, so I will defer that to him, unless you would rather have me——

Senator Dodd. Well, you did comment—at least my impression was, when you talked about no-fault, that compensation such as that, really hadn't been terribly effective. You are certainly familiar with health insurance and home insurance, and unemployment compensation, workman's compensation, rather; haven't they worked pretty well?

Dr. Mason. One of the options considered by our working group and we looked, in total, at eight different possible solutions to the problem—was a no-fault approach. We did not recommend that approach. We are not necessarily opposed to a no-fault system, but neither are we, at this point in time, ready to endorse such a system.

Our present proposal is for changes in the tort system, and then watch to see whether going further is going to be necessary.

Senator Hawkins. Thank you.

Mr. Willmore, we will hear from you at this time.

Mr. Willmore. Good morning, Madame Chairman. I am pleased to be here to present the views of the Department of Justice on the administration's proposal for dealing with the childhood vaccine supply problem. I would ask that my full statement be submitted for the record.

Senator Hawkins. Surely.

Mr. Willmore. I would really like to address myself to the heart of the administration's proposal, which is the ban on punitive damages and the $100,000 cap on noneconomic compensatory damages, such as pain and suffering and mental anguish.

As Dr. Mason explained, the reason behind that proposal is that we feel that this will provide the predictability necessary in a system for the manufacturers of the pertussis vaccine and other childhood vaccines to obtain the necessary liability insurance that they need to produce and distribute the vaccine.

The administration believes that a ban on punitive damages is emminently justifiable for childhood vaccine-injury cases. Indeed, we believe that there is no legitimate role for punitive damages in these cases, and that punitive damages, if anything, jeopardize a program clearly in the best interests of American children.

Punitive damages, as you are aware, are a policy tool, developed by the courts under the common law, to punish defendants for particularly egregious conduct. The theoretical justification for punitive damages, thus, is to deter certain unacceptable behavior.

The need and justification for such deterrence is largely undermined, however, where the product—as with childhood vaccines—already is subject to an exacting regulatory regime designed to protect public health and safety—a regime, I might add, which has significant sanctions available to it, including criminal penalties.

Along with a variety of licensing procedures and restrictions and, as noted, criminal sanctions, applicable statutes and regulations also permit seizures and injunctions. It, thus, is difficult to justify punitive damages where society, as here, has an alternative system in place to prevent the undesirable conduct at issue.

Moreover, as with all policy tools—and punitive damages are very much a judicially created policy tool—important countervailing policies, such as the need to ensure a reliable supply of vaccines, and the advantages of attracting additional producers to the market, may more than overcome the policies that underlie punitive damages.

It is an entirely legitimate role—indeed, a necessary role—for the Government to choose between conflicting benefits to the public and to determine which policies promote the greatest health and safety.

Also significant is that such a ban, in many instances, may expedite settlement of vaccine-related personal injury lawsuits by removing a major impediment. Since one of the primary beneficiaries of punitive damages are plaintiff's attorneys, it frequently is in the attorney's interest to hold out for punitive damages, while the client would be best benefited by getting a quick settlement that could be used for immediate medical and rehabilitative care.

Producers, of course, are almost always unwilling to pay punitive damages, a situation which can readily lead to an impasse between the plaintiff's attorney and the defendant that forces the case to trial and can cause years of delay in the payment of any money to the plaintiff. Accordingly, a ban on punitive damages may facilitate and expedite the quick and reasonable compensation of injured claimants.

Finally, particularly for this area of tort liability, it is highly unlikely that a ban on punitive damages will have any effect on the incentives created by the tort system for producers to ensure that they are producing the safest possible vaccine.

Economic compensatory damages, which are wholly unaffected by the administration's proposal, alone can easily amount to in excess of $1 million for serious brain injury or total disability cases. I can assure you that this is a very powerful incentive.

In this regard, it should be emphasized that claimants will continue to be entitled to a very generous level of benefits under prevailing tort law standards. The administration's proposal does not reduce by 1 penny the complete compensation to which prevailing plaintiffs are entitled for all their medical and custodial care expenses, the cost of all necessary rehabilitative services, and their lost earnings.

Lost earnings alone, for example, readily can amount to well over $500,000. In addition, claimants, under the administration's proposal, are eligible for an award of an additional $100,000 for noneconomic, compensatory damages such as pain and suffering. This ensures that prevailing claimants will receive substantial compensation, more than enough to pay for the necessary medical care and other services that they may need.

I would add a word on to the administration's $100,000 proposed cap for noneconomic compensatory damages. As I've noted, this feature is shared by all other serious legislative proposals under consideration.

The administration's inclusion of such a cap, as I suspect was the motivation for the other authors of legislation under consideration, was motivated by the fact that because such damages are highly subjective, they accordingly are open ended and thereby add to the unpredictability of the vaccine injury liability.

Moreover, there is the entirely practical consideration that without such a cap the ban on punitive damages could be easily circumvented through the simple expedient of relabeling punitive damages as pain and suffering or mental anguish.

It is not, of course, our purpose to deny plaintiffs adequate compensation for their often very real pain and suffering. Indeed, no amount of money can really compensate for the tragedy of a lost or permanently disabled child. Because such compensation is necessarily highly subjective, it is a particularly appropriate subject for legislative limits. The cap, therefore, was set at what we have concluded, as have all others who have proposed legislation in this area, to be the very generous, yet reasonable level of $100,000. And as I have noted, this $100,000 is in addition to an already potentially very generous level of compensation, in excess in some cases of $1 million.

In conclusion, the administration's proposal is designed to correct a problem that jeopardizes the continued supply of pertussis vaccine, and perhaps of all childhood vaccines. It does this with the minimal amount of Federal intervention needed to avoid a serious threat to the health of American children. It does so without creating new entitlement systems, new bureaucracies, or totally rewriting the standards under which compensation is provided pursuant to state tort law. It is a limited, specific solution to a limited, specific problem, and one which we hope will receive the serious consideration of the committee.

I appreciate the opportunity to present the Department's views, and will be pleased to answer any of your questions.

[The prepared statement of Mr. Willmore and responses to questions submitted for the record follow:]

Department of Justice

STATEMENT

OF

ROBERT L. WILLMORE
DEPUTY ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

BEFORE

THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

CONCERNING

S. 827 - CHILDHOOD VACCINE INJURY COMPENSATION

ON

JULY 18, 1985

I am pleased to be here today to present the views of the Department of Justice on the Administration's proposal for dealing with the childhood vaccine supply problem.

As the members of this Committee are aware, the last few years have witnessed a serious threat to the supply of pertussis vaccine as producers of the vaccine have either withdrawn from the market or indicated their increasing difficulty in obtaining the liability insurance necessary to continue distribution of the vaccine. Earlier this year, the Administration was faced with the very real prospect of the then sole remaining supplier withdrawing from the market by as early as July 1--a development which would have had unacceptable adverse health consequences for American children.

As soon as the possibility of this development became apparent, a Cabinet Council Working Group was formed to identify and analyze the reasons for this threat to the supply of pertussis vaccine, and to recommend an appropriate solution. In the short period of time dictated by the imminency of the problem, members of the Working Group met with many of the various actors involved, and convened on an almost weekly basis to review available information and to consider proposed alternatives. The results of these deliberations are summarized in a report prepared by the Working Group, which serves as the basis for the Administration's legislative proposal. In this regard, it should be noted that the success of the Working Group's efforts was in no small part due to the personal leadership of Secretary Margaret Heckler and Acting Assistant Secretary James Mason.

A cessation of pertussis vaccine distribution did not, of course, occur on July 1. Instead, a producer of pertussis vaccine that had earlier abandoned the market reentered, and the until then sole remaining producer apparently found sufficient liability insurance to remain in the market for the present. The Administration has been informed, however, and its own investigations confirm, that this present situation may be only temporary, and that the threat of a pertussis vaccine shortage could easily reemerge. Moreover, the Administration's legislative proposal is directed not only to ensuring that the existing pertussis vaccine producers continue their distribution of the vaccine, but that other pharmaceuticals enter the market so as to end the problematic reliance on only a handful of producers for this vital product.

The reason for the pertussis vaccine availability problem was quickly apparent to the Working Group. As a result of the burgeoning tort liability exposure of all vaccine producers, the insurance industry has concluded that the liability associated with vaccines, particularly with the pertussis vaccine, may be too unpredictable to insure with any degree of confidence. The producers of vaccines, in turn, have indicated their understandable unwillingness to produce such vaccines without adequate liability coverage, lest the entire company--particularly for small to medium sized producers--is forced into bankruptcy as a result of uninsured tort liability on one product line.

It also was not overly difficult for the Working Group to ascertain the source of the unpredictability driving the vaccine supply problem. The source was not so much the number or type of personal injury lawsuits--though there was some obvious concern of the producers about the recent rapid growth in claims--but, rather, the wholly open-ended nature of the potential liability. The producers and insurers seem to have largely reconciled themselves to the fact that there will be a number of lawsuits, and that those lawsuits will result in significant payments to plaintiffs. What they have been unable to reconcile themselves to is the open-ended nature of their liability. They are concerned--quite understandably from recent developments--that while the number and types of such lawsuits can perhaps be predicted within a broad range, the potential level of damages are virtually unpredictable. Of particular significance in this regard is a recent polio vaccine case in which the plaintiff was awarded ten million dollars in damages, eight million dollars of which were in punitive damages.

Accordingly, it was the Working Group's conclusion that the liability associated with childhood vaccines would be more readily insurable if the level of damages available in any single case were more predictable. In that non-economic damages are by far the least predictable component of damage awards, the

Working Group determined that this predictability could be achieved by limiting the non-economic damages awardable with regard to any injury claim. Specifically, the Working Group recommended a ban on punitive damages, and a generous yet reasonable cap on non-economic compensatory damages such as pain and suffering and mental anguish. This cap has been established at $100,000 in the Administration's legislative proposal. The Working Group was aware in this regard that all other serious legislative proposals in this area contain these two limitations, and that there thus appears to be a consensus that unlimited non-economic damages need to be reined in.

A ban on punitive damages is emminently justifiable for childhood vaccine injury cases. Indeed, we believe that there is no legitimate role for punitive damages in these cases, and that punitive damages, if anything, jeopardize a program clearly in the best interests of American children.

Punitive damages, as you are aware, are a policy tool developed by the courts under the common law to punish defendants for particularly egregious conduct. The theoretical justification for punitive damages thus is to deter certain unacceptable behavior. The need and justification for such deterrence is largely undermined, however, where the product--as with childhood vaccines--already is subject to an exacting regulatory regime designed to protect public health and safety; a regime I might add which has significant sanctions available to it, including criminal penalties. Along with a variety of licensing procedures and restrictions--and, as noted, criminal sanctions--applicable statutes and regulations also permit seizures and injunctions. It thus is difficult to justify punitive damages where society, as here, has an alternative system in place to prevent the undesirable conduct at issue.

Moreover, as with all policy tools--and punitive damages are very much a judicially created policy tool--important countervailing policies, such as the need to ensure a reliable supply of vaccines and the advantages of attracting additional producers to the market, may more than overcome the policies that underlie punitive damages. It is an entirely legitimate role--indeed, a necessary role--for the government to choose between conflicting benefits to the public, and to determine which policies promote the greatest health and safety.

Also significant is that such a ban may in many instances expedite settlement of vaccine-related personal injury lawsuits by removing a major impediment to quick settlements. Since one of the primary beneficiaries of punitive damages are plaintiffs' attorneys, it frequently is in the attorney's interest to hold out for punitive damages, while the client would be best benefitted by getting a quick settlement that could be used for immediate medical and rehabilitative care. Producers, of course, are almost always unwilling to pay punitive damages--a situation which can readily lead to an impasse between the plaintiff's attorney and the defendant that forces the case to trial and can cause years of delay in the payment of any money to the plaintiff. Accordingly, a ban on punitive damages may facilitate and expedite the quick and reasonable compensation of injured claimants.

Finally, particularly for this area of tort liability, it is highly unlikely that a ban on punitive damages will have any effect on the incentives created by the tort system for producers to ensure that they produce the safest possible vaccine. Economic compensatory damages, which are wholly unaffected by the Administration's proposal, alone can easily amount to in excess of a million dollars for serious brain injury or total disability cases. I can assure you that this is a very powerful incentive.

In this regard, it should be emphasized that claimants will continue to be entitled to very generous benefits under prevailing tort law standards. The Administration's proposal does not reduce by one penny the complete compensation to which prevailing plaintiffs are entitled for all their medical and custodial care expenses, the cost of all necessary rehabilitative services, and their lost earnings. Lost earnings alone, for example, readily can amount to well over half a million dollars. In addition, claimants may be awarded an additional $100,000 for pain and suffering. This ensures that prevailing claimants will receive substantial compensation--more than enough to pay for necessary medical care and other services that they may need.

I should also add a word on why the Administration is proposing a $100,000 cap on non-economic compensatory damages such as pain and suffering and mental anguish. As I have noted, this cap is a feature shared by all the other serious legislative proposals under consideration. The Administration's inclusion of such a cap was motivated by the fact that because such damages are highly subjective, they also are open-ended and therefore add to the unpredictability of vaccine injury liability. Moreover, there is the entirely practical consideration that without such a cap the ban on punitive damages could be easily circumvented through the simple expedient of relabeling punitive damages as pain and suffering or mental anguish.

It is not, of course, our purpose to deny plaintiffs adequate compensation for their often very real pain and suffering. Indeed, no amount of money can really compensate for the tragedy of a lost or permanently disabled child. Because such compensation is necessarily highly subjective, it is a particularly appropriate subject for legislative limits. The cap therefore was set at what we concluded, as have all others who have proposed legislation in this area, to be the very generous yet reasonable level of $100,000. And, as I have noted, this $100,000 is in addition to an already potentially very generous level of compensation--in excess in some cases of $1,000,000.

In conclusion, the Administration's proposal is designed to correct a problem that jeopardizes the continued supply of pertussis vaccine, and perhaps of all childhood vaccines. It does this with the minimal amount of Federal intervention needed to avoid a serious threat to the health of American children. It does so without creating new entitlement systems, new bureaucracies, or totally rewriting the standards under which compensation is provided pursuant to state tort law. It is a limited, specific solution to a limited, specific problem, and one which we hope will receive the serious consideration of the Committee.

I appreciate the opportunity to present the Department's views, and will be pleased to answer any of your questions.

U.S. Department of Justice
Civil Division

Deputy Assistant Attorney General

Washington, D.C. 20530

Honorable Orrin G. Hatch
Chairman, Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510

Dear Chairman Hatch:

Attached are my responses to the Committee's additional questions regarding my testimony at its recent hearing on childhood immunization.

Sincerely,

Robert L. Willmore
Deputy Assistant Attorney General

Attachment

1. One of the key differences between the Administration's proposal and some of the other proposals that have been recommended is that the Administration's proposal does not involve the creation of an administrative compensation system. Why has the Administration rejected the approach of a compensation system? Why do you think that the tort system modified along the lines you have suggested is superior to an administrative compensation system? What is the advantage for victims in your proposal?

Answer:

The Cabinet Council Working Group on Vaccine Supply and Liability did not recommend an administrative compensation system because it did not believe that creation of such a system was necessary to remedy the current threat to a reliable supply of childhood vaccines.

The establishment of an entitlement program for persons who believe that they have been injured by a vaccine is a major step which we do not believe should be undertaken in the absence of compelling evidence that the existing method of compensating victims through the tort system is inadequate. In this regard, it should be noted that our society relies on the tort system to provide compensation for tens of thousands of personal injury cases every year, many of which involve children severely and permanently injured through no fault of their own. It is unclear why the tort system, as a vehicle for providing compensation, apparently is considered adequate for these tens of thousands of cases every year, yet should be considered inadequate for a relative handful of vaccine-related injury cases.

The potential problems with any administrative compensation system are many and significant. For one thing, an administrative compensation system might reduce incentives for manufacturers and providers of vaccines to exercise due care and invest resources in the development of safer vaccines -- a result which would be clearly contrary to the public interest. In addition, such a system could be extraordinarily expensive. Even if the Federal Government does not bear the cost directly, it will bear much of the cost indirectly through its subsidization of the childhood vaccination programs. The Black Lung disability benefits programs is a powerful example of how difficult it can be to control the size and cost of any administrative compensation program. An additional consideration is that an administrative compensation program could be used as a precedent for other related areas such as medical malpractice or product liability. Considering that any such program is likely to be "no-fault," such a precedent could have significant legal and economic consequences that must be carefully considered. Finally, no[illegible] of the proposed administrative compensation programs are "exclusive" in the sense that claimants are required to use the programs in lieu of the tort system. We are unaware of any existing nonexclusive administrative compensation programs, and believe that lack of exclusivity will create serious problems that may prevent any program from achieving the results for which it is designed.

We do not wish to suggest that the tort system is perfect; it clearly is not. However, we believe that the most promising approach is to identify any serious problems in the tort system, and correct them. This is the approach adopted by the Administration in its legislative proposal for dealing with the vaccine supply problem.

As noted in my statement, the elimination of punitive damages and a cap on non-economic compensatory damages is likely to lead to quicker settlements of vaccine-related injury lawsuits. And, of course, by ensuring that adequate supplies of vaccine will be available, the Administration's proposal will help eliminate conditions that would otherwise lead to thousands of new victims every year.

2. What problem can you anticipate that State court systems will have with your proposal?

Answer:

We do not believe that state court systems will have any problems implementing the Administration's proposal. Indeed, in certain areas some states already cap non-economic compensatory damages or severely restrict or eliminate punitive damages.

3. Isn't your proposal likely to be opposed by attorneys and plaintiffs who believe that there is negligence in the manufacture and administration of vaccines, and in the failure of industry and government to develop better vaccines, and who therefore believe that punitive damages should be awarded?

Answer:

Undoubtedly, some attorneys and plaintiffs will oppose the Administration's proposal. It should be emphasized, however, that to the extent a person is injured as a result of the negligence of a vaccine manufacturer or provider, under the

Administration's proposal that person will receive all his or her economic compensatory damages (which may well exceed a million dollars) plus up to $100,000 in pain and suffering. For the reasons discussed in detail in my statement, punitive damages have no legitimate role in the context of vaccine-related injuries, and have the perverse effect of jeopardizing a program universally recognized to be of great benefit to the public.

4. If the United States Government were to become either the insurer or reinsurer for the manufacturers of vaccines, would you expect the Department of Justice to participate in the defense of lawsuits filed against the manufacturers? Does the Administration either support or oppose the proposal that the United States Government act as insurer of last resort?

Answer:

It is highly likely that the United States would have to become involved in vaccine-related injury lawsuits if it became either the insurer or reinsurer for the vaccine manufacturers. The precise extent of this involvement would depend on the nature of the United States' financial obligations, the legal resources available for participation in such lawsuits, and the litigation relationship between the United States and the manufacturers. It is unlikely, however, that the fiscal interests of the United States would be adequately protected without some active participation by the Department of Justice.

The Administration does not believe that making the Federal Government the "insurer of last resort" is an appropriate or desirable solution to the insurance availability problem currently plaguing the vaccine industry. The Administration believes that the insurance industry is more than capable and willing to provide adequate levels of insurance if the manufacturers' liability for vaccine-related injuries is determined along sensible lines. A federal vaccine insurance program thus would merely treat the symptoms and not cause of the manufacturers' problems.

5. Has the United States Government been named as defendant in any vaccine lawsuits? If so, could you provide a list of these cases and the parties to them. (Senator Stafford)

Aside from the 1,602 suits filed against the United States pursuant to the Swine Flu Program of 1976, we have identified 27 suits alleging injury due to vaccines in which the United States was a party. A list of those cases and the parties, including the districts in which the suits were filed and the civil action numbers of the suits, where known, is attached. We have no readily available means of identifying less recent cases.

6. We all know that the process of suing to recover damages in the court system is a lengthy and expensive one. To the degree that some vaccine injuries are indeed unavoidable, what is wrong with a simpler, less costly, no-fault approach? (Senator Kennedy)

Answer:

This question is largely answered in the response to Question #1. Several additional considerations should be noted, however.

First, it is by no means clear that a no-fault administrative compensation system would be less costly. To the contrary, extensive experience with other administrative compensation programs, such as the Black Lung disability benefits program, suggest that such a program could easily become extremely expensive, and prove to be a far greater financial burden on the vaccine manufacturers and the Federal Government than the current tort system. Thus, any reduction in transaction costs associated with individual claims may be overwhelmed by the increase in the number of claims that may be filed (and the resulting increase in overall transaction costs) for what claimants believe may arguably be vaccine-related injuries.

Second, adoption of a no-fault approach will not significantly simplify the process of determining which claimants should receive compensation. The time and resource consuming issue in vaccine-related injury cases is not fault, but causation; that is, whether the vaccine caused the injury. Because the epidemiological evidence indicates that there are only a handful of childhood vaccine-related injury cases every year, it may be far more cost effective to leave such cases in the tort system which is well designed to ascertain causation, than to incur the significant expenses of creating and administering a no-fault administrative system that may provide only marginal resource savings over the tort system.

Finally, while simplification and cost savings are desirable goals, they should not come at the expense of credible decisionmaking. Many of the proposed administrative compensation systems, however, suffer from that flaw. We believe, for example, that attempts to "predetermine" causation would result in decisions that, while perhaps cheaper to arrive at, may be largely arbitrary and indefensible.

7. Do you have an objection in principle to the Federal government having an insurance or reinsurance authority in reserve in the event it is necessary to assure a continued vaccine supply? Why? How would such an authority be harmful, even if it never needed to be used? (Kennedy)

Answer:

For the reasons discussed in the response to Question #4, it would be inappropriate and undesirable for the United States to insure the vaccine manufacturers. For that reason, such authority should not be enacted.

8. On May 30 of this year, an Administration proposal on vaccine compensation appeared in a newsletter. That proposal included a ban on punitive damages in cases relating to the administration of a vaccine. The draft makes it pretty clear that this is to protect the vaccine manufacturers from claims. How do you justify this proposal? (Senator Metzenbaum)

Answer:

My statement describes in detail the ample justification for a ban on punitive damages.

9. Is the Federal Government vulnerable to liability claims, and can you summarize the experience of the Federal Government in this regard? (Senator Grassley)

Answer:

There are two basic sources of potential government liability arising from childhood immunizations:

(1) liability allegedly incident to the government's regulatory processes; and

(2) liability arising from administration of a vaccine by government personnel (including liability based on failure to warn), or medical malpractice in the care and treatment of a child who has received a vaccine.

As indicated in the response to Question #5, the government has been a party to twenty-seven vaccine suits to date (not including swine flu litigation). A few of the twenty-seven suits do not arise from childhood immunizations. Thus, we have only limited experience. Several, such as the Loge case, arise from the government's regulatory activities.

The Supreme Court's recent decision in United States v. S.A. Empresa de Viacao Area Rio Grandense (Varig Airlines), -- U.S. --, 104 S.Ct. 2755 (1984) makes it clear that the United States has no liability for regulatory activities. This decision will have less impact for litigation falling within category (2). To that extent, the government may be somewhat vulnerable to liability claims.

10. The manufacturers argue that they are unable to get insurance protection at reasonable cost and that this problem threatens to drive them out of producing vaccines. Did your work group satisfy itself that this is a fair statement, and, if so, what was the basis for your conclusion? (Senator Grassley)

Answer:

Yes, it is a fair statement that manufacturers are experiencing considerable difficulty in getting insurance protection at reasonable cost. The Working Group arrived at this conclusion based on the discussions of some of its members with vaccine manufacturers and representatives of the insurance industry, its analysis of the deteriorating vaccine insurance market over the past few years, and the fact that several manufacturers have recently left the market on the stated grounds of the unavailability of adequate insurance at reasonable rates.

11. You have stressed that the Administration's proposal carefully makes only minimal changes in the tort claims system. What, in your opinion, are the broader implications, if any, for product liability litigation if we make the adjustments you suggest or that are suggested in the Madigan Bill?

Answer:

It is difficult if not impossible to assess fully the broader implications at this time. However, it is plain that tort law currently is presenting serious difficulties for certain sectors of our economy, including the production of childhood vaccines. An obvious response to these problems is to enact reasonable reforms to tort law which permit those valuable activities to continue, while protecting the fundamental function of tort law to compensate persons who have been injured by the wrongdoing of others. In the case of childhood vaccines, the most desirable and effective reform appears to be a ban on punitive damages and a cap on non-economic compensatory damages. For other areas, other reforms may be more appropriate. Enactment of the Administration's proposal would suggest that Congress at least is willing to entertain reasonable tort reform proposals where there is a legitimate need for such reform.

CAPTION	DIST/STATE		CIVACT
Allison, Jo Ann et al v. Merck & Company, Inc., et al	D	NY	
Andrulonis, Joanna et al v. U.S. et al	N	NY	79-847
Artrip, Gianna NF (Paul E)	E	LA	83-867N
Baker, Wade v. U.S.	S	CA	84-0474
Barnett	D	MD	K78-644
Berkovitz, Kevan by his Parents Arthur & Donna	W	PA	84-2893
Berry, Mary Sue et al v. Pfizer et al	S	AL	81-280H
Boruski, Valerie v. U.S. et al	N	IL	81-6461
Cartwright, Robert G. et al v. U.S. et al	W	WA	85-524
Duke, Dale et al v. Merck, et al	D	CA	
Farrall, William & Anne	N	OH	79-5
Garlington, Pamela Dianne v. Merck, et al	D	LA	
Hallock, Stewart et al v. Merck & Co.	D	NY	
Hitchcock	D	DC	77-1138
Holcomb, Kelli et al v. U.S. et al	S	WV	79-2376
King, Lori & Ken v. Lederle Labs	W	AR	81-5005
Lemar, Alice et al	W	TN	
Levin, Edward	D	NM	81-865
Levin, Edward v. U.S.	D	NM	81-865HB
Loge, Lora E & Roger S.	W	AR	79-5088
Mansoor, John et al v. LA, U.S. et al	D	LA	
Moore, Robert Lee v. SEC, USN	M	FL	80-70THOM
Peloquin, Ronald J & Paulette L.	E	AR	LR80-514
Schindler	E	MI	7-72707
Shanklin, Carter A. v. U.S., Wyeth Lab	N	GA	78-1443A
Wagner, Don Eric	S	CA	74-420N
Wilson, Gregory S. et al	N	GA	80-1325A

Senator HAWKINS. Mr. Willmore, I believe you used to work for OMB, is that correct?

Mr. WILLMORE. I came to the Department of Justice in early June. I was at the Office of Management and Budget for 2½ years prior to that, and was a member of the working group that Dr. Mason chaired.

Senator HAWKINS. Isn't OMB's opposition to this bill based on the opposition to the precedent of no-fault and how that would affect Superfund and asbestos compensation, for just two instances, rather than the merit?

Mr. WILLMORE. Clearly, what you have noted is a consideration, though I would not say that it is the central reason for the administration's concern about a no-fault precedent.

As we heard from Senator Stafford today, there will be those who will take any legislation enacted in this area and attempt to use it as a precedent in areas such as asbestos and hazardous waste.

Senator Dodd in his question did not mention his amendment to the Kasten bill, which would establish a no-fault compensation system. I understood his question as directed more to his amendment than the legislation before the committee today.

We do not think that any solution in this area should serve as a precedent. But clearly, it will be used by some as a precedent, which will be a very complicating factor.

Senator HAWKINS. But isn't this, in your opinion, a unique situation? We mandate that parents must immunize their children; we don't mandate they have to use asbestos in the schools, we didn't make that a rule.

Mr. WILLMORE. No; and I want to emphasize that whatever solution is eventually enacted, assuming one is, we will be the first to argue that this is a unique situation. The trouble is that there will be others who will be arguing to the contrary. You have identified one aspect that is unique. I think there are other aspects that are also unique.

Nevertheless, many persons who have spoken today have referred to the innocent victim and the need to ensure compensation of the innocent victim. I believe that was implicit in Senator Stafford's statement. It was clearly explicit in Senator Dodd's question.

The argument that we need to ensure the compensation of the innocent victim is certainly not unique to the vaccine area. It is a problem that is found in many areas: medical malpractice, product liability, hazardous waste. And, as you have heard from both Senator Stafford and Senator Dodd, there will be an attempt to use this legislation as a vehicle for pursuing a number of other agendas.

Senator HAWKINS. But do you endorse punitive damages even for grossly negligent violation of FDA standards?

Mr. WILLMORE. We do not believe that punitive damages are necessary for violations of FDA standards for the simple reason that we already have available sanctions for such violations, including criminal penalties. That is one of the unique aspects of vaccines. If a company produces a toaster and is grossly negligent in the production of the toaster, there is no body of readily available regulations and statutes to prosecute that company criminally. Nor are there available all the regulatory sanctions and statutory sanctions which the FDA and HHS posses.

However, for vaccines, those sanctions exist. Accordingly, the need for punitive damages is clearly attenuated.

Senator HAWKINS. Are you implying that this is no-fault?

Mr. WILLMORE. I'm sorry; the administration's proposal is not no-fault.

Senator HAWKINS. So the administration is saying there is fault involved?

Mr. WILLMORE. The administration's proposal only affects state tort law in the limited sense of banning punitives and capping non-economic compensatory damages.

To the extent that fault is part of the system, that depends on the tort law of the various States. Each State has its own standards for determining when a defendant is liable. If a State has a negligence basis of liability or a strict product basis of liability, or if a State develops a no-fault basis of liability, that would be the applicable standard. The administration's proposal does not, in any sense, affect that applicable standard. It only affects the damages to be awarded once liability is determined.

Senator HAWKINS. Even though the State legislation is modeled after the CDC model legislation and the vaccine, in the great percentage of instances, is procured from the Government, from the Federal Government, the vaccine itself is purchased from the Federal Government?

Mr. WILLMORE. Yes; there clearly is Federal involvement. I'm not sure whether it's purchased from the Federal Government, or how the Federal Government is involved in the chain of distribution, but there is Federal involvement. Dr. Mason can address that better than I can.

Senator HAWKINS. But from a legal standpoint, is that not important?

Mr. WILLMORE. From a legal standpoint—not, I believe, in the suits against the manufacturers. The manufacturers have raised the argument, in some situations, I believe, that the fact that this is a federal program establishes, in essence, a form of a defense.

My understanding is that that argument has never prevailed.

Senator HAWKINS. What does your bill do for the parents of an injured child who can't sue because of difficulty proving negligence?

Mr. WILLMORE. Well, there are, of course, two things that a claimant ultimately has to prove: causation and fault. The portion of the administration's proposal that deals with the tort law system does not really affect either aspect. We do recommend the creation of a commission to consider these issues, and I suppose that would be one of the questions it would consider.

A parent who brings a vaccine-injury lawsuit, in any State, would be subject to the same requirements of law that any parent who has an injured child from any other cause——

Senator HAWKINS. Basically, first, they would have to get a lawyer?

Mr. WILLMORE. Yes; first, they would have to get a lawyer.

Senator HAWKINS. And you heard Mrs. Judd say she couldn't get a lawyer.

Mr. **Willmore**. Well, I believe she said she eventually found a lawyer.

Senator **Hawkins**. Quite some time had elapsed.

Mr. **Willmore**. There is no shortage of tort lawyers in our society, Madame Chairman. Indeed, there are a lot of tort lawyers out there. While I do not want to make an uncategorical statement, if someone has a viable claim, the chances of getting a tort lawyer to represent you in court are extremely high.

The fact of the matter is that many people are getting lawyers to represent them in all sorts of proceedings, not just tort proceedings in court. Many people are using lawyers for Social Security disability cases, and feel that without a lawyer they are not really capable of pursuing their claim. While I do not agree with that view, that is, in fact, the case.

Lawyers thus are finding their way into our compensation systems. I think they are going to be an integral element of any administrative compensation system, whether it's ex parte, or whatever. Lawyers are going to be part of any compensation system.

Senator **Hawkins**. That's true, but the present system, because of the lack of information distributed to the parents who take their child to the physician or to the clinic to get the Government-mandated shots, leaves the parents helpless. They don't, in many instances, even know that the injury came from the shot—under the present system.

We hope that that will change, with information given to the doctors. The doctors and physicians are now cooperating 100 percent, putting notices up in the waiting room, giving pamphlets to the parents to read before the child has the shot, notifying the parent that they certainly shouldn't have the second shot if they have any adverse reaction to the first. That's all been happening maybe in the last 18 months, that this has happened, and we have no idea, in the absence of mandated reporting of adverse reactions by the physician to the Government—we have no idea how many children are injured. We have no idea how many children have been permanently injured.

All these figures and all the things we're talking about, what it's going to cost, are hypothetical because we do not know. We are in a situation where the number of injuries may be very small. If it is as small a number as the administration says, it certainly is a saving of money to give awards to these parents and keep the cost of the shot down.

What is happening, as you are seeing, is tremendously increasing costs for vaccines: $26 million increase for polio, $22 million increase for DTP; these million dollar increases in the costs of vaccination because it may hurt a very few the administration is saying it is very few, and those very few have a right to go to court with a perfectly good lawyer.

We have a lot of documented evidence that they do not even know they should get a lawyer. Just lately, we have this phenomenon of being on the parents' side, those parents who are participating in a Government-mandated shot, in the common good, so we don't have epidemics in the entire United States.

It seems to me, although the administration, the CDC, HHS, and every other initial you can think of for an agency that has done study after study after study since 1974, and it's 1985, that we would have some compassion and some budget compliance saying: "It's cheaper to do it now than to wait. Let's do it now, it may not be these millions and millions and millions." And that we would have the cooperation of the administration instead of having the administration as an enemy, and I have to go get all these votes to overcome what you think is good legislation. We would like you to be on our side for a change.

I don't mind—I like to fight—but I don't like, in the meantime, every child that was taken in today for their first DTP shot not having adequate information, nor recourse to anyone to keep their home from being foreclosed upon. It's not just buying the little casket—that's a big expense for a lot of families, as we've heard today from Mrs. Judd—it's not just buying the little casket to bury one of your twins—I don't think you would take $1 million for one of your twins, if you had twins. Do you have twins?

Mr. WILLMORE. No, I don't have any——

Senator HAWKINS. Do you have any children?

Mr. WILLMORE. No.

Senator HAWKINS. Would you give them a DTP shot, if you did?

Mr. WILLMORE. I think I would, yes.

Senator HAWKINS. And, indeed, would value the life of that child, because you would prevent it from having this incidence of high injury that we get if you have the disease.

Mr. WILLMORE. I'm sorry, I——

Senator HAWKINS. You know you prevent your child from getting the disease.

Mr. WILLMORE. Right.

Senator HAWKINS. That's what it is all about.

Mr. WILLMORE. That is correct.

Senator HAWKINS. In the common good; but we know there is a fraction of the population that has adverse reactions—it's a fact.

Mr. WILLMORE. That is correct.

Senator HAWKINS. And I don't understand why we don't just all sit around here at the table this afternoon and say, "Let's see, for a year's period of time, how many adverse reactions are reported by physicians," because now we are going to mandate that reporting, and it may be a miniscule number and we may be not fighting huge budget numbers out there.

Mr. WILLMORE. Senator, the reporting requirement, of course, is distinct from the compensation requirement.

Senator HAWKINS. Surely.

Mr. WILLMORE. And it is not one that I can address, though I understand that part of the problem is the relationship of the physicians to the Government. That is something that Dr. Mason is far more capable of addressing.

As to the compensation issue, I would simply reiterare that many people are injured in our society. Indeed, a lot of innocent people are injured in our society, and many of them are children. We, as a society, for well over a century have used a system for compensating people for personal injuries of this type—the tort system.

The tort system is not perfect, but it is the system that we use for tens of thousands of cases every year—many of them just as tragic as some of the cases we have discussed today. It is not clear to us that the tort system cannot handle these cases, or should not handle these cases. It is handling tens of thousands of other very tragic cases.

There is a supply problem, which we have to do something to resolve. The administration's proposal would correct that problem. But we continue to believe that the tort system will work in these cases, just as it works in the tens of thousands of cases that are being brought through it every year, including many cases involving injured or deceased children where vaccines are not at issue.

Senator HAWKINS. We thank this panel for participating in this record, which we will continue to compile by calling our next panel, comprised of representatives of manufacturers of the DTP vaccine.

Mr. Robert Johnson will be speaking for Lederle Labs, a division of American Cyanamid Corp.; Mr. David Williams and Mr. Stephen White will be testifying for Connaught Labs; and Mr. Charles F. Hagan will present testimony on behalf of Wyeth, a division of American Home Products.

We would ask that those that would like to leave the room would do so quietly. We have a vote at 12 o'clock, and this Senator has to make the vote. Those that would like to remain may do so, also quietly.

Mr. Robert Johnson will be speaking first, on behalf of Lederle Labs.

Mr. Johnson.

STATEMENTS OF ROBERT JOHNSON, PRESIDENT, LEDERLE LABORATORIES, ACCOMPANIED BY RONALD CRACAS, LEGAL COUNSEL, AMERICAN CYANAMID CO.; DAVID J. WILLIAMS, VICE PRESIDENT, CONNAUGHT LABORATORIES, INC., ACCOMPANIED BY CARL GRECO, GENERAL COUNSEL, AND STEPHEN WHITE; AND CHARLES F. HAGAN, VICE PRESIDENT AND GENERAL COUNSEL, AMERICAN HOME PRODUCTS, ACCOMPANIED BY DANIEL SHAW, VICE PRESIDENT FOR MEDICAL AFFAIRS, WYETH LABORATORIES

Mr. JOHNSON. Madame Chairman, I am Robert Johnson, President of Lederle Laboratories, a Division of American Cyanamid Co., and I am accompanied today by Ronald Cracas, our legal counsel for American Cyanamid Co.

As you requested, I will summarize our written statement and submit it, as well as a background paper, for the record.

Lederle is now the sole manufacturer and distributor of oral polio vaccine, and one of two suppliers of DTP vaccine. Today, our commitment to supplying vaccines is seriously threatened by a dramatic upsurge in liability.

It is our view that the answer to this problem lies in Federal legislation that can provide the stability needed for the continued manufacture and development of vaccines while, at the same time, ensuring fair compensation for legitimate vaccine-injury claims.

Let me emphasize that Lederle's vaccines meet all the stringent safety and efficacy standards required by the U.S. Government, and are manufactured in accordance with our own strict quality-control measures. Nonetheless, we are being barraged with an assault of lawsuits.

At this time, the total dollar demand against Lederle in childhood vaccine litigation exceeds $2 billion. Only a few cases have proceeded to trial, and we have successfully defended about half of them. In other cases, juries have sometimes awarded staggering sums, for example, $10 million in one polio case, including $8 million in punitive damages.

In this environment, it is impossible to prepare any sensibie projections of future liability exposure. Providing adequate protection for manufacturers, through either pricing or insurance, is therefore increasingly difficult.

It should be noted that the number of carriers willing to insure Lederle this year dropped from 26 to 8. This reflects insurers' concerns about the growing number of suits filed, rising defense costs, and the increasing number and size of settlements and awards.

After months of negotiation, Cyanamid was able to purchase partial insurance coverage for the 1-year period beginning July 1, 1985. Under our new policy, we face dramatically higher premiums for substantially less insurance.

Madame Chairman, we must reluctantly face the fact that last year's vaccine pricing is inadequate to cover the projected costs of liability for this year. To provide for such expenses, we must raise our prices; and as of July 24, our oral polio vaccine price will be $6.26 per dose, and our DTP vaccine price will be $4.29 per dose.

We made every effort to avoid pricing increases, despite the financial burdens of this business. Virtually all of the additional revenues generated by these price increases will be devoted to liability costs, and may not be adequate for that purpose if current trends in jury verdicts continue.

At Lederle, we are convinced that the best combination of desirable features to establish a predictable level of vaccine-injury compensation can be found in H.R. 1780, the bill introduced in the House of Representatives by Congressmen Madigan and Broyhill.

H.R. 1780 would create a simple, no-fault hearing mechanism, designed to award fair and prompt compensation, to be paid for by the manufacturer or the health care provider.

H.R. 1780 avoids creating a bureauracy to administer surcharges, Government funds, or Government-backed insurance systems. H.R. 1780 assures the continued availability of childhood vaccines by providing the predictability that manufacturers need in order to get sufficient insurance. It accomplishes this by imposing a ceiling on the awards that can be granted to persons who claim to have been injured by vaccines, a limit that is high enough to care for even severely injured persons, but also gives reasonable predictability for manufacturers and health care providers.

S. 827 takes a somewhat different approach, and we agree with a number of the points that you have made, but we would like to highlight for the committee a few of the major, substantive problems with S. 827.

It does not address the problem of excessive and unpredictable judgments awarded in the tort system. S. 827 would add a no-fault compensation system on top of the current unlimited tort system. We feel this makes the current problem worse, not better.

The use of a surcharge to compensate injured persons seems unnecessarily complex. We also have doubts about the administrative feasibility of a no-fault system, based on a legislatively defined table of injuries.

While we believe that legislation is needed to protect the Nation's vaccine supply, it is not the only solution that we are pursuing. We are hopeful that Lederle's research efforts eventually will provide a more direct answer.

Lederle now has in place a multimillion dollar biological research effort that aims, among other things, to develop a new pertussis vaccine which may have fewer adverse reactions than present products. A final vaccine product is still 3 to 5 years away. As long as it is economically feasible, we will continue to supply these essential vaccines and develop new ones.

Madame Chairman, I thank you, and will be happy to answer any questions.

[The prepared statement of Mr. Johnson and responses to questions submitted for the record follow:]

Statement By
Robert B. Johnson
President
Lederle Laboratories Division, American Cyanamid Company
Before The
Senate Labor and Human Resources Committee
Vaccine Injury Compensation Legislation

July 18,1985

VACCINE INJURY COMPENSATION HEARING

LEDERLE STATEMENT

JULY 18, 1985

Introduction

Since its founding in 1906, the Lederle Laboratories Division of American Cyanamid Company has had a continuous commitment to the development, manufacture and distribution of the life-saving vaccines required to meet public health needs.

Today that commitment is seriously threatened by a dramatic upsurge in liability that could drive us from the marketplace through the imposition of excessive awards by the courts.

It is our view that the answer to this problem lies in federal legislation that can provide the stability needed for the continued manufacture and development of vaccines while at the same time insuring fair compensation for legitimate vaccine injury claims.

Over the past years the number of manufacturers of vaccines has been in steady decline. Relatively low profit margins, increased manufacturing costs, and very difficult clinical testing have all played a role in the decline. At present, the most important factor is excessive litigation and excessive awards. In fact, the recent onslaught of vaccine injury claims is an ever growing threat to continued vaccine production.

Production and Distribution

Lederle is now the sole manufacturer and distributor of oral polio vaccine (ORIMUNE®) and one of two suppliers of DTP vaccine (TRI-IMMUNOL®). The production of these essential vaccines involves complex and lengthy processes. In addition, in order to maintain an ongoing program there has to be a major commitment to scientific research and development.

In an effort to meet the nation's demand for essential DTP vaccine, Lederle has expanded its Pearl River, N.Y., facilities to produce enough vaccine to meet the nation's needs. This is estimated by the Centers for Disease Control to be about 18 to 20 million doses annually. In the past twelve months our capital expenditure for the renovation and expansion for increased DTP manufacturing was over $5 million.

We are proud that we now have the capacity to meet the nation's DTP needs. We are also gearing up to resume production and distribution of adult and pediatric tetanus-diphtheria vaccines, which have been temporarily deferred in order to allocate our resources to DTP production.

But now that another manufacturer has resumed DTP vaccine distribution, we will adjust our production according to market demands. Because the lead time from initial start-up to final release for TRI-IMMUNOL is 10 months, any change requires sufficient adjustment time. The lead time for ORIMUNE is 18 months.

Liability Claims

We believe that it is wrong to penalize manufacturers for producing vaccines which conform to standards established by the Federal Government for use in immunization programs mandated by state governments. We are being asked to bear the costs of injuries allegedly attributed to our vaccines, even though we are not at fault.

Let me emphasize that Lederle's vaccines meet all stringent safety and efficacy standards required by the U.S. government and are manufactured in accordance with our own strict quality control measures. Nonetheless, we are being barraged with an assault of lawsuits associated with our vaccines.

At this time the total dollar demand against Lederle in childhood vaccine litigation exceeds $2 billion. We now face some 115 cases with several claiming more than $150 million.

The claims against other manufacturers undoubtedly would add billions more to the total. Since industry sales of childhood vaccines are only a small fraction of this total, it is clear that something must be done, especially since the situation is rapidly getting worse. The trend is most evident in the DTP cases. All but two of the more than ninety cases against us have been filed since 1982, even though we have been distributing DTP vaccine for over forty years. The cases filed so far this year are almost double the 28 cases filed all last year.

Only a few cases have proceeded to trial, and we have successfully defended about half of them. But in other cases, juries have sometimes awarded staggering sums: $10 million in one polio case (including $8 million in punitive damages), $3.2 million in another polio case, and $1.1 million in a DTP case. In this environment, it is impossible to prepare any sensible projections of future liability exposure. Providing adequate protection for manufacturers through either pricing or insurance is therefore increasingly difficult.

Insurance Status

The number of carriers willing to insure Lederle this year dropped from 26 to 8. After months of negotiations, Cyanamid was able to purchase partial insurance coverage for the one year period beginning July 1,1985. Under this new policy we face dramatically higher premiums per unit of coverage, a significant rise in the amount of self-insurance, and a drastic reduction in the limits of insurance. These increases in premiums for substantially less insurance coverage reflect insurers' concerns about the growing number of suits filed, rising defense costs, the increasing number and size of settlements and awards, and the emergence of new theories of manufacturer liability.

In addition, in many states there is no coverage for punitive damages.

Costs

With insurance now covering only a fraction of the exposure from the spiraling vaccine-related injury litigation, we find ourselves in an extremely tenuous situation. Lederle is constantly faced with the possibility of unpredictable court and jury awards which may exceed the total sales of vaccines for one or more years. We recognize our obligation to produce vaccines, but at the same time we cannot ignore our obligations to stockholders and employees.

Mr. Chairman, based on recent trends for vaccine associated litigation, we must reluctantly face the fact that last year's vaccine pricing is inadequate to cover the projected costs of liability during the coming year. In addition, we have to set aside funds for suits filed that may not be settled for several years.

To provide for such expenses we must raise prices. As of July 24, ORIMUNE will cost $6.26 per dose, and TRI-IMMUNOL will cost $4.29 per dose. The previous prices were $5.11 and $2.80 respectively.

We made every effort to maintain our prices, despite the financial burdens of expansion, research and litigation. However even these price increases may not be adequate if current trends in jury verdicts continue.

We remain hopeful that legislation will provide the predictability necessary to offset this pattern of rising prices brought on by spiraling litigation and insufficient insurance.

Predictability

We urge Congress to enact legislation that would establish a level of predictability in vaccine injury compensation. Predictability will enable vaccine manufacturers to anticipate compensation costs in vaccine prices.

Lederle believes such legislation should provide speedy, certain and fair compensation for the small number of persons unavoidably injured by childhood vaccines administered to protect the public health. It should also significantly reduce the unpredictable and excessive liability that vaccine manufacturers face.

At Lederle we are convinced that the best combination of desirable features can be found in H.R. 1780, the bill introduced in the House by Representatives Madigan and Broyhill.

H.R. 1780

Availability of Vaccines

H.R. 1780 responds to the need to assure the continued availability of childhood vaccines by providing the predictability that manufacturers need in order to get sufficient insurance. It accomplishes this by imposing a ceiling on the awards that can be granted to persons who claim to have been injured by vaccines-- a limit that is high enough to care for even severely injured persons, but also gives reasonable predictability for manufacturers and health-care providers.

Compensation

H.R. 1780 would create a simple, no-fault hearing mechanism designed to award fair compensation rapidly and inexpensively. This compensation would be paid for by the manufacturer or health-care provider whose product or conduct caused the injury. Under provisions of the bill, payments would be made promptly, with disputes over the division of responsibility among respondents postponed for a later proceeding. By employing this kind of simple mechanism, H.R. 1780 avoids creating a bureaucracy to administer surcharges, government funds, or government-backed insurance systems.

Hearing Panels

H.R. 1780 establishes expert hearing panels to review medical evidence on causation and reaches a reasoned judgment about the relationship between a covered vaccine and the claimed injury. Fairness is assured by giving both the claimant and the respondent the power to choose one expert, with the third expert to be chosen by the first two experts.

We believe that H.R. 1780 provides the soundest basis for a legislative program designed to deal with the issues before the Committee.

S. 827

The bill introduced by Senator Hawkins, S. 827, takes a somewhat different approach. We agree with a number of the points Senator Hawkins has made about the problems covered by that bill, and we feel she has performed an important public service by making sure that these issues are promptly addressed. But we would like to call to the Committee's attention a few of the major substantive problems we have with S. 827 as currently drafted.

Excessive and Unpredictatable Judgments

The most important defect in S. 827 is that it does nothing to address the problem of excessive and unpredictable judgments awarded in vaccine cases processed through the tort system. Under S. 827, a no-fault compensation system is added on top of the current unlimited tort system. The bill allows those persons who would lose a tort suit to file for no-fault compensation. It then simply adds those costs to the already excessive -- and unpredictable -- costs health-care providers and manufacturers are bearing today. We feel this makes the current problem worse, not better.

Surcharge

The use of a surcharge to compensate injured persons seems unnecessarily complex. It would be difficult, if not impossible, to administer such a fund in an environment where the types of products and identity of manufacturers are constantly changing.

We also have doubts about the administrative feasibility of a no-fault system based on a legislatively defined table of injuries. The medical conditions listed in the table are likely to cause more confusion and uncertainty than they resolve, especially as scientific knowledge develops and expands over the years. In addition, we are concerned that the bill lacks any meaningful statute of limitations.

AMA and Administration Proposals

Two other vaccine injury compensation proposals have been circulated by the AMA and the Administration. While we commend the AMA and the Administration for their recognition of the need to limit the rapidly escalating size of tort awards in vaccine cases, we are concerned that imposition of only a partial limit -- one that leaves compensation panels or juries free to award an unlimited amount under the label of "economic damages" -- will not in fact solve the problem.

We think that the best combination of desirable features for a vaccine compensation bill can be found in H.R. 1780, and we urge the Committee to seriously look at that proposal as it prepares the final version of a legislative solution to the vaccine problem.

Investment in Vaccine Research

While we believe legislation is needed to protect the nation's vaccine supply it is not the only solution that we are pursuing. We are hopeful that Lederle's research efforts eventually will provide a more direct answer.

Throughout its 80-year history the company has pioneered the development of many vaccines. Lederle now has in place a multi-million dollar biological research effort that aims, among other things, to develop a new pertussis vaccine which may have fewer adverse reactions than present products. An acellular vaccine is currently undergoing intensive preclinical development and will enter clinical trials next month in cooperation with researchers at U.C.L.A. However, a final vaccine product is still three to five years away. In addition to our improved pertussis vaccine, our current vaccine development encompasses three other major programs: haemophilus influenzae type b, herpes and polio.

The total cost of bringing a new vaccine to market, through completion of clinical trials, is estimated to be in the range of 40-50 million dollars. The company invests these funds with no guarantee that the product will make it to the marketplace.

Lederle is the only company that has effectively supplied the country with live, oral trivalent polio vaccine. We have consistently supplied DTP vaccine for over 40 years.

As long as it is economically feasible, we will continue to make every effort to supply these essential vaccines and develop new ones.

Mr. Chairman, I thank you and the members of this Committee for this opportunity to express our position. If you have questions I will be glad to answer them.

Responses to Questions

based on

U. S. Senate Hearing, July 18, 1985

COMMITTEE ON LABOR AND HUMAN RESOURCES

By:
Robert B. Johnson
Lederle Laboratories

Question

(1) Would you please provide a breakdown of the factors that contributed to your most recent price increase for the DPT vaccine? Can you provide data to the Committee to document the amount of this increase that is directly attributable to higher insurance costs? What percentage of the price increase reflects increased expenditures for vaccine research and, particularly, for research to develop an improved pertussis vaccine?

Answer

The major factor that contributed to Lederle's recent price increase for DTP vaccine was the increased self insurance requirements under our new insurance program. For the policy year ending June 30, 1985, 26 carriers were willing to insure Lederle. Of the first $60 million of insurance under last year's policy, Lederle was self-insured for about $13 million. Because of insurance carriers' concerns about the growing number of lawsuits filed, rising defense costs, and the increasing number and size of settlements and awards, only 8 carriers are insuring Lederle for the 1985-1986 period. Of the first $60 million of insurance under our new policy, Lederle is self-insured for about $41 million. Therefore, our 1985-1986 potential uninsured liability is over three times greater than last year. In addition, our insurance premiums doubled and the overall coverage within our insurance program declined dramatically.

Because of our reduced insurance coverage, it was obvious that last year's vaccine prices would have been inadequate to cover our projected liability costs. In addition, we have to set aside funds for suits filed that may not be resolved for several years.

Virtually all of the additional revenue generated by the recent price increases will be devoted to liability costs and even this major increase may not be adequate for that purpose if current trends in jury verdicts continue.

Although we are continuing a costly and intensive research program to develop a safer DTP vaccine, these expenditures were not a major factor in our recent price increase.

Question

(1-A) We have had very rapid increases in prices of vaccines, and, in fact, I think that there was yesterday or will be today the announcement of another increase in the price of DPT vaccine.

If the Congress provides an acceptable legislative solution to this liability/compensation problem, will you assure us that you will roll back your prices for these vaccines in a quick and expeditious manner?

Were the Congress to provide a legislative solution, is there anything you can think of which would delay rolling back prices?

Answer

Virtually all of the additional revenue generated by the recent price increases will be devoted to liability costs and may not be adequate for that purpose if current trends in jury verdicts continue. If the current unfavorable environment for vaccines improves in the future, such as through passage of effective legislation limiting awards for vaccine injury compensation, Lederle will adjust our prices for TRI-IMMUNOL and ORIMUNE as the liability exposure permits. However, Congress should be aware that legislation might not have an immediate impact on price. Legislation might even result in a temporary price increase to the extent that it encourages additional claims for compensation to be filed. If the exposure is high during the initial adjustment period, it would require us to raise our prices in the short term. After this initial period, during which a full assessment of long term costs would be made, we would adjust our prices according to the degree of liability exposure.

Question

(2) If Congress were unable to pass legislation that addresses the problems identified in your testimony, what is the possibility that you will not remain in the vaccine business?

Answer

If the current trend of spiraling litigation continues or worsens, there is no guarantee that it will be economically possible for us to stay in the business. Unless some predictable outlook can be placed on liability costs, there is a very real possibility that we will be forced to abandon the vaccine business.

Question

(2-A) The testimony of Mr. Schwartz, who proceeded you on Panel Two, provided us with a number of questions which might well be asked of your Panel and of the earlier administration panel.

Let me ask you to address a question that he raised in his testimony; namely: What is the significance of the "Koehler memorandums"; to which Mr. Schwartz refers in his testimony?

Answer

The memorandum demonstrates that for some time scientists from the various manufacturers have been exploring questions concerning the validity of the toxicity test and possible ways to improve the toxicity testing of the vaccine. Despite continued global efforts, no one has yet been able to demonstrate a better test procedure.

Question

(3) Do you believe that the DTP vaccine you are currently manufacturing is the safest possible product? How do you respond to allegations that industry is not doing all that can be done to improve vaccines, particularly the pertussis vaccine?

Answer

The current whole cell pertussis vaccine is the only type of pertussis vaccine that has been shown to be safe and effective. It is manufactured in accordance with our own strict quality control measures and the stringent safety and efficacy standards enforced by the federal government.

Today's pertussis research efforts focus on acellular vaccines. Lederle has had an acellular vaccine under development since 1981 and hopes to begin clinical trials in cooperation with researchers at U.C.L.A. later this year. Only recently have advances in scientific technology provided new directions in the understanding of the pertussis organism and identifying the components most likely to be immunogenic. As in the case with any new drug, development of Lederle's acellular vaccine must move from tests with laboratory animals, through initial safety tests in humans, immunization studies and large-scale clinical trials before it can achieve FDA approval for general use.

Question

(4) What is your problem with the solution posed to the vaccine compensation issue in S. 827? Why can't you support this approach?

Answer

As I stated on July 18, the most important defect in S. 827 is that it does nothing to address the problem of excessive and unpredictable judgments awarded in vaccine cases processed through the tort system. S. 827 simply adds the no-fault compensation costs to the already excessive and unpredictable litigation costs health-care providers and manufacturers are bearing today. We feel this makes the current problem worse, not better.

The use of a surcharge to compensate injured persons seems unnecessarily complex. It would be difficult, if not impossible, to administer such a fund in an environment where the types of products and identity of manufacturers are constantly changing.

We also have doubts about the administrative feasibility of a no-fault system based on a legislatively defined table of injuries. The medical conditions listed in the table are likely to cause more confusion and uncertainty than they resolve, especially as scientific knowledge is dynamic and continues to expand. In addition, we are concerned that the bill lacks any meaningful statute of limitations.

Question

(5) Do you believe consumers should be allowed to sue on the grounds of gross negligence wherever such grounds exist?

Answer

The U.S. Department of Justice addressed this question during the hearings on July 18, 1985 in the statement by Robert L. Willmore, Deputy Assistant Attorney General, as follows:

> "A ban on punitive damages is emminently justifiable for childhood vaccine injury cases. Indeed, we believe that there is no legitimate role for punitive damages in these cases, and that punitive damages, if anything, jeopardize a program clearly in the best interests of American children.
>
> Punitive damages, as you are aware, are a policy tool developed by the courts under the common law to punish defendants for particularly egregious conduct. The theoretical justification for punitive damages thus is to deter certain unacceptable behavior. The need and justification for such deterrence is largely undermined, however, where the product--as with childhood vaccines--already is subject to an exacting regulatory regime designed to protect public health and safety; a regime I might add which has significant sanctions available to it, including criminal penalties. Along with a variety of licensing procedures and restrictions--and, as noted, criminal sanctions--applicable statutes and regulations also permit seizures and injunctions. It thus is difficult to justify punitive damages where society, as here, has an alternative system in place to prevent the undesirable conduct at issue.
>
> Moreover, as with all policy tools--and punitive damages are very much a judicially created policy tool--important counter-vailing policies, such as the need to ensure a reliable supply of vaccines and the advantages of attracting additional producers to the market, may more than overcome the policies that underlie punitive damages. It is an entirely legitimate role--indeed, a necessary role--for the government to choose between conflicting benefits to the public, and to determine which policies promote the greatest health and safety.

Answer (continued)

(5)

> Also significant is that such a ban may in many instances expedite settlement of vaccine-related personal injury lawsuits by removing a major impediment to quick settlements. Since one of the primary beneficiaries of punitive damages are plaintiffs' attorneys, it frequently is in the attorney's interest to hold out for punitive damages, while the client would be best benefitted by getting a quick settlement that could be used for immediate medical and rehabilitative care."

We agree with the Justice Department's position that there already are enough powerful incentives for vaccine manufacturers to provide the safest and best vaccines possible.

Question

(6) What is the cause of the vaccine shortage we have been experiencing lately?

Answer

The principal reason for the steady attrition of vaccine manufacturers from the marketplace has been the unlimited risk of liability associated with childhood vaccines.

Throughout the 1980's there were three manufacturers of DTP in the U.S. - each distributing approximately one-third of the nation's needs.

In June 1984 Wyeth announced a withdrawal from the market citing excessive liability risks. Shortly thereafter, Connaught restricted the distribution of their vaccine because of an inability to obtain insurance. To help meet the nation's needs for this essential vaccine, Lederle immediately negotiated an agreement to purchase additional doses from Wyeth to supplement our production. This purchase agreement required Lederle to defend virtually all litigation that may occur as a result of Wyeth DTP vaccine. In addition, we spent $5 million to expand our Pearl River facility so that we could triple our output of DTP vaccine. However, due to the long lead-time for production and testing requirements of additional vaccine, we were not able to compensate for Connaught's estimated one-third of the market to prevent a shortfall of supply which was felt during the December 1984 through April 1985 time period.

Question

(7) There has been a great deal of attention focused on the fact that manufacturers of the DPT vaccine have been driven from the market because they can't get insurance. Could you elaborate on this?

Answer

As indicated in my statement of July 18, 1985, the number of carriers willing to insure Lederle this year dropped from 26 to 8. After months of negotiations, Cyanamid was able to purchase partial insurance coverage for the one year period beginning July 1, 1985. Under this new policy we face dramatically higher premiums per unit of coverage, a significant rise in the amount of self-insurance, and a drastic reduction in the limits of insurance. These increases in premiums for substantially less insurance coverage reflect insurers' concerns about the growing number of settlements and awards.

With insurance now covering only a fraction of the exposure from the spiraling vaccine-related injury litigation, we find ourselves in an extremely tenuous situation. Lederle is constantly faced with the possibility of unpredictable court and jury awards which may exceed the total sales of vaccines for one or more years. We recognize our obligation to produce vaccines, but at the same time we cannot ignore our obligations to stockholders and employees.

Question

(8) The Committee has received two documents (attached). One is a 1967 internal Lederle memorandum that states that Lederle's vaccine produced more adverse reactions than the then-produced Lilly vaccine. Quoting from the document: "In case of male, for pain, irritability, and temperature, Lederle injections had significantly higher rates of reaction where as in case of females, for swelling and temperature, Lederle injection had significantly higher percent of reaction..." In addition, the Committee received a copy of a 1972 letter from a product service manager for Lederle responding to a doctor about the relative reactivity of the two vaccines. Quoting from that letter: "We are aware that Lilly has developed a method whereby a none cellular pertussis vaccine is obtained by fractionalization of the pertussis component. Although this part of the procedure is different, both our Medical Advisory and Quality Control staffs state there is no reason to suspect that our Tri-Immunol is any more reactive than Lilly's." How do you explain this contradiction?

Answer

It has never been established that there is or ever was a vaccine with fewer severe reactions. Lederle and the medical scientific community here and abroad have for many years tried to develop a pertussis vaccine that would provide full protection but with a lower potential for producing reactions of the kind associated with the current vaccine.

Eli Lilly and Company manufactured and distributed a split-cell pertussis vaccine during the 1960's and part of the 1970's. While there have been anecdotal reports, and even a small clinical comparison by Lederle, suggesting that the Lilly vaccine was associated with fewer of the mild, transient reactions encountered with DTP vaccine, it has never been demonstrated that the Lilly vaccine caused fewer severe reactions. It must be noted that no relationship between the incidence of mild, transient reactions and the incidence of severe reactions has been established. In a clinical study of whole-cell vaccine and a Lilly-like split-cell vaccine, the only serious reactions occurred in children who received the split-cell vaccine. Further, an FDA advisory panel of experts expressed concern about the efficacy of the split-cell vaccine, and neither Lilly, which removed the product from the market, nor the company which purchased Lilly's rights to the split-cell vaccine has thus far satisfied this concern.

Question

(9) Will you please provide the Committee with the following information?

A list of all lawsuits filed aginst you during the last five years in connection with DPT vaccine.

A list of each of your insurance companies for each of the last five years and a statement of the coverage provided and the premiums paid. Also, please provide a list of claims paid under these policies.

Answer

The following information depicts the number of DTP lawsuits filed against Lederle during each of the last five years:

1980	1
1981	1
1982	9
1983	13
1984	28
7/31/85	51
Total	103

We have previously furnished the Committee responsive information in confidence regarding details of insurance coverage, premiums and claims experience. However, the recent avalanche of claims coupled with the small number of suits resolved to date, makes historical data virtually meaningless.

Question

(10) An organization called Advocates for a Safe Vaccine, and the parents organization, "DPT," have provided us with a report containing information, including documents obtained through discovery, regarding what is alleged to be the failure of the industry to pursue development of a safe pertussis vaccine, and the industry's lack of forthrightness about the safety of the vaccine. If you do not have a copy of this report, entitled "D.T.P. Vaccine: Interim Report," the Committee can provide it to you. Will you please respond to the report, either specifically, point by point, or at least in general. Can you at the minimum respond to the overall thrust of the report, which seems to be (a) the industry has been well aware for some time of the need to develop a safer vaccine and has had the knowledge and techniques to do this, but has not done so; and (b) the current test for toxicity is recognized to be outdated and inaccurate, yet industry has continued to use this test, thus marketing a product with uncertain toxicity.

Answer

The Advocates for a Safe Vaccine are, in fact, a group of plaintiffs' lawyers who are suing the vaccine manufacturers for enormous damages on a contingent fee basis. Their so-called "Interim Report" is not a scientific paper. It is a biased argument based oupon selected portions of the many documents the vaccine manufacturers have in their files. The documents are selected out of context in an attempt to show that the manufacturers had it within their power to develop a better vaccine, but for some perverse reason, refuse to do so.

Unfortunately, contrary to the assumption the plaintiffs' lawyers seem to make, scientists cannot discover improved or better products on demand. This is particuarly true in the case of the pertussis vaccine. As indicated recently in the report issued by the Institute of Medicine on "Vaccine Supply and Innovation," the pertussis bacterium has been unusually slow in yielding its biological secrets (page 18). If any manufacturer could have developed a better vaccine, it certainly would have done so. Lilly attempted to do it with its Trisolgen vaccine, but was not entirely successful. Lederle has explored a number of alternatives but has, thus far, not met with success. Our recent efforts toward development of an acellular vaccine are described in the answer to question 3.

With regard to the portion of the question concerning the toxicity test, the answer is the same as the answer to question 2A.

Question

(11) What are the prospects that your vaccine research will produce a better pertussis vaccine in the near future?

Answer

Since the current vaccine has an excellent efficacy record, research efforts are pursuing development of a vaccine that might be less reactive.

New technology and scientific progress is contributing to a better understanding of the pertussis organism. Specific components of the cell are now being studied separately for their immunizing effect and reactions in animal models. As a result, it now appears possible to develop candidate vaccines which may be less reactive.

Lederle plans to start clinical trials with our acellular vaccine later this year. As is the case with any new drug, development must move from tests with laboratory animals, through initial safety tests in humans, immunization studies and large-scale clinical trials before it can achieve FDA approval for general use. This process can take up to five years. Even after licensure, it will require long-term use of the new vaccine, accompanied by careful epidemiological studies to determine if a superior vaccine has been developed.

Question

(12) How much do you spend on research on a safer pertussis vaccine?
What percentage is this of your company's profits?
What percentage is it of your profits from the sale of the DTP vaccine?

Answer

The total cost of bringing a new vaccine to market, such as acellular pertussis vaccine, is estimated to be in the range of $40 - $50 million dollars. This estimated cost includes both basic research and the necessary clinical trials to prove safety and efficacy.

Since Lederle's acellular pertussis research program was initiated in 1981 and will most likely continue through the early 1990's, the expenditures for this program will be prorated over several years. Obviously, the costs of this program will be greatest during the period when large scale clinical efficacy trials are being conducted. Therefore, since research costs vary from year to year, it is impossible to calculate these costs as a percentage of our Company's profits. In addition, the profitability of DTP vaccine cannot be determined without providing for large uncertain contingent liabilities.

Senator HAWKINS. Thank you, Mr. Johnson.

Mr. Williams.

Mr. WILLIAMS. Madame Chairman, good morning. We are happy to be here today to address this committee on the various issues of concern. We recognize the need for the time constraints and, as such, have put together a summary for reading today.

With me today is Attorney Carl Greco who is general counsel for Connaught, Stephen White from Reed-Stenhouse, which is Connaught's insurance broker, and we hope Stephen can inform the committee today about some of the problems that have occurred over the last few years, and behind me is Dr. Don Metzgar who is vice president for operations and has responsibility for the manufacture of DTP.

Connaught continues to strongly endorse the concept of a fair compensation system for certain vaccine-related injuries. We applaud your efforts to date, and are pleased that you are affording us the opportunity to work with you in continuing this process.

We have provided written testimony today addressing the status of Connaught's production and distribution of DTP, the current selling price of DTP and associated costs, the current status of Connaught's product liability insurance, the need to predict liability claims, and the cost of such claim , a review of the Hawkins and the Madigan bills, pending in the Senate and the House, respectively; and, finally, Connaught's investment in vaccine research.

With regard to the status of Connaught's production of DTP and its distribution, I'm happy to report that on April 25, 1985, we were able to resume full distribution of DTP here in the United States. This followed the successful conclusion of over 9 months of efforts to secure new insurance agreements.

We feel confident at this point that our current stream of product being produced should support our historic rates of supplying 30 to 40 percent of this Nation's requirements for this very vital vaccine.

In reference to the selling price of DTP, Connaught's catalog price has been $2.80 per dose since May 1983. During our testimony back in December to the House of Representatives, I indicated at that time that a price increase would be contemplated and would coincide with the resumption of full distribution of DTP. That has now occurred, and over the next few weeks we will be finalizing the cost of our new insurance agreements, and will be in a position to adjust our selling prices upward to reflect those increased costs.

Congress is now considering two alternative vaccine compensation systems. It is our feeling that to meet the overall objectives, any compensation system must be predictable as to both the number and amount of potential product liability claims.

It is, therefore, the position of Connaughr Laboratories, Inc., that any childhood vaccine injury compensation system should provide for an exclusive remedy, available to individuals injured as a result of receiving certain childhood vaccines.

The current pending legislation, S. 827 and H.R. 1780, while a step in the right direction, do not go far enough to permit an indefinite, continued supply of vaccines at a reasonable price, inasmuch as both pieces of legislation provide for an alternative remedies under the tort system.

We believe that the need to be able to predict liability claims, and the cost of such claims, is paramount to the success of any Federal compensation program.

Mr. Stephen White who, as I mentioned, is here with me today will be later addressing that issue from the insurance industry's point of view.

There are other important areas of the two bills that we think are worthy of the review of this committee. We feel that the Table of Injuries, included as part of S. 827, is too broad, and believe that only those adverse reactions that are clearly defined as vaccine related and having permanent residual effects should be included in the scope of any act.

It is our opinion that the private hearing panel, provided for in H.R. 1780, is a more effective means of disposing of vaccine-related injury claims.

H.R. 1780 is not, however, without its areas requiring the attention of this committee. It is felt that there should be mandatory reporting by health care providers, including but not limited to the lot number and manufacturer of the vaccine used, and also mandatory reporting of all serious adverse reactions. We believe that this will allow us to get a better handle on the frequency of adverse reactions as they occur in this country. We feel that that is extremely important.

This identification would further aid in the identification of the specific manufacturer of the vaccine alleged to have caused the injury.

At this time, I would like to pass the microphone to Mr. Stephen White, and look forward to any questions that you might have after this testimony of industry is complete.

Thank you very much for this time.

[The prepared statement of Mr. Williams and responses to questions submitted by Senator Hatch follows:]

STATEMENT BY

DAVID J. WILLIAMS, VICE PRESIDENT & GENERAL MANAGER

CONNAUGHT LABORATORIES, INC.

SWIFTWATER, PENNSYLVANIA

SENATE SUB-COMMITTEE ON LABOR & HUMAN RESOURCES

CONNAUGHT LABORATORIES, INC.

Testimony to Senate Labor and Human Resources Committee

"Childhood Immunization: Problems and Options"

July 18, 1985

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Connaught is pleased to have the opportunity to comment on the several issues that the Senate Labor and Human Resources Committee wishes to address in their hearing entitled, "Childhood Immunization: Problems and Options". We continue to endorse the efforts of Congress to create a structure which allows the appropriate compensation of those who experience injuries following immunization. We applaud Congress' efforts to date and are pleased that we are being afforded the opportunity to work with you in continuing this very important process.

This written testimony will address the following important areas:

1. The Current Status of Connaught's Production of our Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, USP (hereinafter DTP) and its Distribution.
2. The Current Selling Price of DTP and Associated Costs.
3. The Current Status of Connaught's Product Liability Insurance.
4. The Need to be able to Predict Liability Claims and the Cost of Such Claims.
5. Comments on the Hawkins and Madigan Bills Pending in the Senate and House, Respectively.
6. Investment in Vaccine Research.

CONNAUGHT LABORATORIES, INC.
Testimony to Senate Labor and Human Resources Committee
"Childhood Immunization: Problems and Options"
July 18, 1985

1. The Current Status of Connaught's Production of DTP and Its Distribution.

For the period July 1, 1984 to April 25, 1985 Connaught limited distribution of DTP to existing city, county, state and hospital contracts. This situation was brought about because of Connaught's inability to renegotiate adequate product liability insurance coverage at the time of the July 1, 1984 product liability insurance policy renewal. On April 25, 1985 we resumed full distribution of DTP vaccine in the United States. This followed the successful conclusion of appropriate new insurance agreements. Given the fact that production had continued during our period of restricted distribution, approximately 2.2 million doses of DTP vaccine were available at that time. Because of a significant immediate demand placed upon Connaught for the product, shipments of the vaccine have significantly outpaced production of the product and, as a result, our inventory as of July 12, 1985 was somewhat less than a million doses. Historically, Connaught's market share has ranged between 30% and 40% of the total US requirements for DTP vaccine. While we consider the current level of inventory that is on hand as tight, we feel confident that the current stream of product being produced should prospectively support those historic rates.

2. The Current Selling Price Of DTP And Associated Costs.

The current catalog price for DTP is $42.00 per vial. This has been Connaught's price since May 20, 1983. It should be pointed out, however, that a significant price increase is expected in the very near future. As was indicated in our previous testimony before the House of Representatives Subcommittee on Health and the Environment in December of last year, a price increase was contemplated to coincide with our resumption of full distribution reflecting our increased cost of insurance. During the next few weeks we will be finalizing the cost of our new insurance agreements and will be adjusting our selling price upward to reflect those increased costs.

Product liability insurance continues to be one of the most significant costs of providing DTP and for that reason any major increase in the cost of insurance will have an immediate impact on the selling price of the product.

3. The Current Status of Connaught's Product Liability Insurance.

As is the case with all vaccine producers supplying the US market, securing product liability insurance has always been difficult. Only a limited number of suppliers will consider the coverage for vaccines and their premium rates have always been substantial. In the past year the problem has become particularly acute. We are no longer able to purchase limits of coverage in amounts previously purchased, regardless of premium costs. Most insurers are now offering extremely limited coverage with premiums at a level heretofore not experienced in our industry. Other insurers have simply withdrawn from insuring vaccine manufacturers entirely; many others decline to continue with our insurance or participate in any new programs. Our current insurance, which became effective in April of this year, is a three year agreement. There are, however, several clauses which will allow termination of coverage should the situation deteriorate to any large extent, beyond what it is today, with regard to the level of claims being made on DTP cases as well as the level of awards accruing from the current tort system. The key to continuing with traditional insurance coverage leads to the next topic of discussion, that is the need to be able to predict liability claims and the cost of such claims.

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4. **The Need To Be Able To Predict Liability Claims And The Cost of Such Claims.**

Most states and the District of Columbia have laws in force which require vaccination against polio, diphtheria, tetanus, pertussis, measles, mumps and rubella as a requirement for attending school. Although rare, some recipients may encounter serious adverse reactions as a result of receiving these vaccinations. The tort system is currently the only way that these injured persons can seek compensation. Although these injuries are seldom, if ever, the result of negligence by persons administering the vaccine or by the manufacturer, courts have understandably sought to compensate these innocently injured individuals. In this regard, the tort system tends to be inconsistent since it neither guarantees compensation to those who fully deserve it, nor prohibits those with frivolous claims from seeking compensation. In addition, and most importantly, awards for similar injuries can vary greatly depending on the jurisdiction and court in which the case is filed. This situation has resulted in a great deal of uncertainty for the insurance companies involved. In calculating a premium for any products liability coverage, the insurance company must be able to calculate both the frequency and the severity of claims. The tort system cannot provide the required predictability. Because of the over whelming importance of the issue of predictability, Connaught is including as part of its testimony a statement by Stephen J. White who is Vice President of Reed Stenhouse Limited of Toronto, Canada. Reed Stenhouse Limited is the insurance broker for Connaught Laboratories. His statement is attached.

5. Comments On The Hawkins And Madigan Bills Pending In The Senate And House, Respectively.

Congress is now considering alternative vaccine compensation systems. It is Connaught's opinion that a fair compensation system should accomplish the following:

1. Attract and maintain the financial resources and expertise necessary to develop new vaccines and improve the current ones.
2. Provide fair and timely remuneration in those rare instances where a vaccine related injury occurs.
3. Encourage the general public to participate in vaccination programs.
4. Encourage the medical community to continue to administer vaccines.
5. Encourage the continued production of current vaccines.

Connaught Laboratories Inc., strongly endorses the concepts of a fair compensation system for certain vaccine related injuries. On April 2, 1985 Senator Paula Hawkins introduced Bill S.827. At that time it was stated that the bill would accomplish four major objectives.

1. Stabilize the supply of childhood vaccine in the US.
2. Control the rapidly increasing costs of mandated vaccines.
3. Provide incentives for the development of safer vaccines.
4. Provide just and expeditious methods for providing compensation for those few children that do suffer from adverse reactions to vaccines.

CONNAUGHT LABORATORIES, INC.

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It is the position of Connaught Laboratories, Inc that any childhood vaccine injury compensation system should provide for an exclusive remedy available to individuals injured as a result of receiving certain childhood vaccines. Legislation providing for compensation on elective basis, that is, legislation permitting a choice between proceeding through the current tort system or accepting compensation under the legislation, will not avoid the current adverse impact upon the continued availability of desirable childhood vaccines. S.827 by its terms permits an election by a person assumed to have suffered a vaccine related injury to pursue compensation from the fund or pursue civil action under the current tort system. Thus, irrespective of the seriousness of the injury, a claimant, on advice of counsel, could weigh the value of the claim under the federal compensation system against the potential value of a civil action arising out of the same incident. Requiring a manufacturer to contribute to a trust fund designed to provide compensation for those childhood vaccine related injuries while continuing to permit the manufacturer to be exposed to liability under the tort system, in perhaps amounts greater than that which the legislation would provide, would in effect be double jeopardy and the anticipated increased cost would be a further threat to the supply of vaccines at a reasonable price as well as providing a chilling effect on the development of new vaccines. Therefore, if manufacturers incur the cost of both systems this double jeopardy would be a deterent to vaccine production and research and a threat to the existance of reasonably priced products.

H.R. 1780 attempts to remove the need for an election by requiring a claimant to file a petition with a hearing panel as a condition precedent to pursuing any traditional civil litigation. Both the administrative and judicial proceedings will be subject to the limitations of damages provided by the act. However, H.R. 1780 does not result in the reduction or elimination of the transaction costs incurred by manufacturers in defending DTP claims. Such reduction or elimination will go far to meet objectives of any proposed vaccine compensation system, and can be accomplished best by enactment of an exclusive remedial compensation scheme.

A further concern of S.827 is the compensable injury table and time limits. It is our opinion that private hearing panels selected from a list of those experts compiled by HHS as provided in H.R. 1780 should hear claims and the panel should determine whether any injuries alleged in the claim are vaccine related injuries.

A review of bill S.827 identifies several areas of concern with the table of injuries. Our purpose in presenting these at this time is to strengthen the impact of the bill if a table of injuries is to be included.

CONNAUGHT LABORATORIES, INC.
Testimony to Senate Labor and Human Resources Committee
"Childhood Immunization: Problems and Options"
July 18, 1985

Our recommendations are as follows:

1. Only permanent injuries should be compensable. Many of the conditions proposed to be compensable are transient, and the focus of the compensation bill should be on those having permanent damage that can clearly be associated with the administration of a vaccine.

2. The proposed time periods for the first manifestation of a vaccine-induced condition are too long:

   (a) Vaccine-related encephalopathy should include any significant acquired damage resulting in impairment of brain function occurring within three days of a DTP vaccination. In determining whether or not an encephalopathy is related to vaccine administration, the entire medical record should be reviewed.

(b) By definition, acute anaphylaxis occurs within minutes and the shock-like syndrome within hours of inoculation. These are transient and should not be compensable unless there are permanent complications clearly resulting from these episodes.

3. The nature of significant vaccine related adverse reactions require delineation, and the proposed prospective studies outlined by the bill could be important steps in defining the nature of these problems. We agree that an active recordkeeping system including but not limited to identity of manufacturer and lot number, and a reporting system of all reactions by health care providers should be provided.

CONNAUGHT LABORATORIES, INC.
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"Childhood Immunization: Problems and Options"
July 18, 1985

4. We believe that only those adverse reactions that are clearly defined as vaccine related and have a permanent residual injury should be included within the scope of this act. Until a broader classification of reactions can be delineated, it is problematic to include injuries that have historically been related to vaccines on an anecdoctal basis, often on only a temporal or chance basis. As further data become available these definitions may be altered.

5. We agree that preexisting disease must be considered in evaluating the patient. Disease existing at the time of the immunization may not be clinically evident. Although such diseases may be aggravated by the immunization or predispose to an adverse reaction, the role of the immunization in such circumstances is often uncertain and it may be impossible to clarify relative contributions. The need for careful evaluation for pre-existing disease emphasizes the importance of the extensive evaluations.

6. The determination of compensation should consider the nature of the injury, the presence of pre-existing disease, and the pattern of improvement or deterioration.

As set forth above, it is our opinion that the private hearing panel provided for in H.R. 1780 is a more effective means of disposing of DTP claims. H.R. 1780 is not without its shortcomings, however. Under this proposal, any person who participated in manufacture, distribution, sale, or administration of the dose or doses of the vaccine alleged to have caused the claimant's injury could be named as a respondent in the hearing panel proceding and, in fact, be found jointly and severally liable to the claimant. This statutory language results in creation of enterprise liability for those entities who have market presence. For example, a claimant might file against all companies who, past or present, engaged in the manufacture of the vaccine. By merely alleging that such manufacturer participated in the manufacture of the dose or doses of the vaccine alleged to have caused the claimant's injury, such manufacturer could be held responsible by the hearing panel. True, the hearing panel is able to determine and find that a particular respondent did not so participate. However, as a practical matter, the compensation scheme provided by H.R. 1780 would result in an award against all manufacturers of the vaccine alleged to have manufactured the vaccine which caused the claimant's injury. The claimant is not required under this proposal to show which vaccine caused the injury. Under current law, product identification is a very significant issue with respect to which each plaintiff bears the burden of proof. In many cases, a manufacturer is able to extricate itself from a position of possible liability by showing that the product involved was not manufactured by the particular corporation. It is felt that manufacturers should not be required to relinquish the requirement that a claimant establish product identification as a condition precedent to a successful claim. In addition, under H.R. 1780, liability determined at the administrative level is to be apportioned pro rata over the respondent parties. The practical result of this is to impose a greater share of liability on a particular respondent than might otherwise be determined under the current tort system. Again, in order to stimulate the manufacture and distribution of vaccines at reasonable prices, it is submitted that liability should be imposed and assessed on a sound factual and legal basis, other than the mere joinder of a respondent in a particular administrative proceeding.

6. Investment in Vaccine Research.

Connaught is involved in substantial research and development activities covering a wide range of technologies and biological products. This is supported by the fact that over the last three years well over 10% of gross sales, and in excess of 15% of sales for its parent, has been expended to fund such research activities. The company's number one priority research project is a less reactive pertussis vaccine. The company regards research and development projects as confidential and proprietary in nature and as a matter of routine does not disclose the particulars thereof.

In summary, we endorse the concept of a bill to create a structure which allows for appropriate compensation of individuals who experience injury following mandated immunization. Continued acceptance of the immunization program is a national priority, worthy of everyone's support.

We applaud your efforts, support your direction and hope that you will incorporate our recommendations into the final version of this important bill.

CONNAUGHT
LABORATORIES, INC.
Swiftwater, Pennsylvania 18370

September 16, 1985

United States Senate
Committee on Labor and Human Resources
Room 4230 Attn: Mr. Powell
Washington, DC 20510

Dear Mr. Powell:

Attached are the responses to the questions raised by the members of the Committee on Labor and Human Resources, to be answered for the hearing record.

Mr. Stephen White's responses are also included as an attachment.

I hope you will find these responses satisfactory.

Sincerely yours,

David J. Williams
Vice President &
General Manager

DJW:mlv

Attachments

(1) Would you please provide a breakdown of the factors that contributed to your most recent price increase for the DPT vaccine? Can you provide data to the Committee to document the amount of this increase that is directly attributable to higher insurance costs? What percentage of the price increase reflects increased expenditures for vaccine research and, particularly, for research to develop an improved pertussis vaccine?

Response

From May 20, 1983 to April 25, 1985, Connaught had maintained a catalogue price for DTP at $2.80 per dose. Connaught was required for half of that time to necessarily restrict full distribution of DTP due to our inability to obtain acceptable insurance coverage. In April of this year, acceptable insurance coverage was obtained and Connaught has resumed full distribution, however, not without an increased cost of insurance.

Litigation defense costs and product liability insurance continue to be the most significant cost of providing DTP and for that reason an increase in the cost of the product has been necessary.

Connaught Laboratories is involved with substantial research and development activities regarding many products including an improved pertussis vaccine. As an indication of this, please note that over the last 3 years well over 10% of gross sales has been expended to fund such activities. As you might well expect, however, Connaught regards research and development project involvement as confidential and cannot disclose the exact particulars thereof.

In addition to the above, we have made significant expenditures on capital equipment; as well, we have incurred the normal increase in labor and material costs.

(2) If Congress were unable to pass legislation that addresses the problems identified in your testimony, what is the possibility that you will not remain in the vaccine business?

Response

There is always a possibility that Connaught will be unable to remain in the vaccine business. As previously disclosed, the unavailability of acceptable product liability insurance coverage, or significant restrictions placed upon Connaught's ability to distribute the vaccine by our insurers will undoubtedly have an impact upon our ability to remain as a distributor of DTP and other vaccine products. Connaught Laboratories, Inc., is the only major vaccine supplier solely dedicated to biological and vaccine products. As such we are committed to providing properly licensed vaccines. We sincerely urge Congress to adopt legislation addressing the issues before it so that we may never face a situation wherein this country is without a source of any valuable vaccine.

(3) Do you believe that the DTP vaccine you are currently manufacturing is the safest possible product? How do you respond to any allegations that industry is not doing all that can be done to improve vaccines, particularly the pertussis vaccine?

Response

The vaccine manufactured by Connaught Laboratories, Inc., is the best product available which can be properly distributed in the United States today. Our expenditure for research and development programs previously alluded to, and were more fully set forth in our written statement provided to this Committee, responds to the allegations leveled against our industry regarding improvement of vaccines.

The DTP vaccine we are currently manufacturing is the only licensed product available. The manufacturing of this product is in accordance with the FDA Act. While we (and others) are constantly searching for improvements, the process is complex.

With regard to what this industry has been doing, all one has to do is look at the record of the biological industry over the past 30 years. The golden age of preventative medicine has occurred in the past three decades beginning with polio, followed by measles, mumps, rubella, pneumococcal, meningococcal, hepatitis, and lately H flu b.

(4) What is your problem with the solution posed to the vaccine compensation issue in S. 827? Why can't you support this approach?

Response

I believe that our statement which was prevously provided to this Committee effectively addresses this question and I direct your attention to paragraph 5 at pages 6 through and including 13 of our written statement as our complete response to this question.

(5) Do you believe consumers should be allowed to sue on the grounds of exist?

Response

Yes - It is not the desire of Connaught Laboratories, Inc., or the industry, to obtain insulation from our negligence. However, where a vaccine is manufactured, tested and distributed in accordance with the scrutiny required by mandatory federal regulations, a claim of negligence should not be expected.

(6) What is the cause of the vaccine shortage we have been experiencing lately?

Response

As we indicated in our previous testimony before the House of Representatives Sub-committee on Health and the Environment in December of 1984, restrictions were placed on full distribution by Connaught Laboratories, Inc., of its DTP vaccine. This restriction did not help to create a shortfall in the availability of DTP vaccine. This is due to the fact that our market share in the previous year was only minimal (a few percentage points), the primary cause of the shortage was in all probability due to the combination of the exit of one of the other two providers and testing problems experienced at the OBRR.

(7) There has been a great deal of attention focused on the fact that manufacturers of the DPT vaccine nave been driven from the market because they can't get insurance. Could you elaborate on this?

Response

I believe that question 7 was answered by Stephen White in his testimony and subsequent questions.

(8) We understand that you have recently negotiated what might be considered to be a fairly risky insurance policy, just to be able to re-enter the DTP market. Why are you willing to take that risk?

Response

Connaught Laboratories, Inc., is a company dedicated to the manufacture of vaccines.

We consider our new insurance agreements to be appropriate to allow the resumption of full scale distribution that took place on April 25, 1985.

(9) Will you please provide the Committee with the following information:
A list of all lawsuits filed against you during the last five years in connection with DPT vaccine.
A list of each of your insurance companies for each of the last five years and a statement of the coverage provided and the premiums paid. Also, please provide a list of claims paid under these policies.

Response *

*(Editor's Note: Due to its relevance to pending litigation, the material comprising the response to question 9 was retained in the file of the Committee.)

(10) An organization called Advocates for a Safe Vaccine, and the parents organization, "DPT," have provided us with a report containing information, including documents obtained through discovery, regarding what is alleged to be the failure of the industry to pursue development of a safe pertussis vaccine, and the industry's lack of forthrightness about the safety of the vaccine. If you do not have a copy of this report, entitled "D.T.P. Vaccine: Interim Report," the Committee can provide it to you. Will you please respond to the report, either specifically, point by point, or at least in general. Can you at the minimum respond to the overall thrust of the report, which seems to be (a) the industry has been well aware for some time of the need to develop a safer vaccine and has had the knowledge and techniques to do this, but has not done so; and (b) the current test for toxicity is recognized to be outdated and inaccurate, yet industry has continued to use this test, thus marketing a product with uncertain toxicity.

Response

a) We produce our product using the state-of-the-art procedures as licensed by the FDA. We share in the desire to produce the safest possible vaccines. Since we commenced business, pertussis has been a very high priority R&D project. To date our best efforts have not met with success, however, we are optimistic about development in the next 3-4 years.
b) The tests we run and the procedures we use are mandated by the U. S. government through Title 21, Code of Federal Regulations. Industry cannot unilaterally use a different test or procedure.

(11) What are the prospects that your vaccine research will produce a better pertussis vaccine in the near future?

Response

Please refer to our written testimony provided to this Committee on page 14.

(12) How much do you spend on research on a safer pertussis vaccine? What percentage is this of your company's profits? What percentage is it of your profits from the sale of the DTP vaccine?

Response

Please refer to our written testimony provided to this Committee at page 14.

Senator HAWKINS. Mr. White.

Mr. WHITE. Thank you. I am Stephen White, I am a vice president of Reed-Stenhouse, Ltd, who are insurance brokers and include, amongst their clients, Connaught Laboratories.

I have prepared a detailed paper, setting out the advice and information I can present to this committee with respect to the matter of product liability insurance, vital to the manufacturers of childhood vaccines. That paper is to be entered into the record, and this will be a brief statement.

The history of product liability coverage is changing to the extent that insurance companies are severely restricting their policy coverage, assuming they will write the insurance coverage at all.

The product liability insurance market does not exist in isolation to deal solely with vaccines, and insurers are facing mounting losses from many areas, including pharmaceutical claims, asbestos claims, and pollution liability claims.

The current insurance market has virtually withdrawn from the provision of product liability insurance on the traditional occurrence policy form, and only the very limited claims made form is now available. Further, the number of insurers that will write the cover at all has been severely curtailed to the extent that many manufacturers cannot buy satisfactory limits at all.

Those insurers that are offering the cover may well have a reduced financial rating, which further antagonizes the difficulties of the manufacturers of vaccines.

The short-term recovery of the insurance market is not at all likely. Companies have been seriously undermined financially, and the only likelihood of their returning to provide insurance will be the strong prospect of securing profits from underwriting.

The difficulties for manufacturers in presenting their risks to insurers tie in with two vital aspects for underwriting insurance: One, establishing the frequency potential of losses; and, two, establishing the severity for the overall market exposure.

The courts have also effectively eliminated recognized defenses for manufacturers, being: One, negligence in manufacture. Courts have now overruled, in many cases, this point of law, whereby a plaintiff simply has to establish that a product was manufactured and that an injury occurred to succeed on the basis of strict liability.

The duty-to-warn defense is also being overruled by many courts, whereby the notices in packages of vaccines, which are realistically available solely to the medical attendant, are deemed inadequate to the parents of injured children.

Courts are also overruling the policy wordings of insurance companies where it was intended that specific exclusions should apply. An underwriter, who set a premium based on covering certain limited aspects of a manufacturer's risks, can find a court demanding that the policy limits be paid simply because the policy has been issued and plaintiffs must be dealt with, ignoring the contract terms drawn between two informed parties.

The legislation proposed by yourself, Senator Hawkins, and the legislation proposed by Congressman Madigan do not limit the liability issue to a simple no-fault compensation system. As long as the prospect of full litigation exists, with the unknown degree of severity of loss, then the insurance market will not willingly return to provide the broad form of product liability insurance required by manufacturers.

Both bills exclude claims of punitive damages; but, again, these exclusions only apply within the compensation system. The prospect of heavy, noneconomic awards, being compounded by the addition of punitive damages, makes the supply of vaccine equally impossible, from a manufacturer's point of view.

In many cases, punitive damages are not payable by insurers, but by a manufacturer. No manufacturer can risk a totally destructive punitive award.

The proposal of Congressman Madigan has the merit, in my opinion from an insurer's point of view, save for the fact that the right to litigation remains in full without a dollar limit. Congressman Madigan's proposal for a compensation system, with a $1 million limit on money compensation, will have the most promising results, from an insurer's point of view, if that legislation is amended to remove the potential but unlimited litigation lawsuits.

If litigation is to be permitted, a dollar limit must be maintained in that area, as the alternative will be unacceptable to the manufacturers, from a risk, cost point of view.

That completes my statement.

[The prepared statement of Mr. White and responses to questions from Senator Hatch follow:]

STATEMENT BY

STEPHEN J. WHITE, F.C.I.I.
VICE-PRESIDENT

REED STENHOUSE LIMITED
TORONTO, CANADA

TO THE

SENATE SUB-COMMITTEE ON LABOUR & HUMAN RESOURCES

REVIEWING THE BILLS OF SENATOR HAWKINS
AND CONGRESSMAN MADIGAN PROPOSING THE ENACTMENT OF
A "NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION
ACT" HEARING ON JULY 18, 1985.

INTRODUCTION

In my role as an insurance broker, I have been asked to appear before the United States Senate Labour & Human Resources Committee at a hearing entitled "Childhood Immunization: Problems & Options" with respect to the difficulties of providing product liability insurance to the manufacturers of these particular vaccines.

I worked in the insurance industry for the past 20 years, the last 14 of which have been in Canada, and my work since 1977 has included an extensive amount of activity in securing product liability insurance for suppliers to the U.S. marketplace. I personally have been engaged in placing product liability for a vaccine manufacturer from 1977.

Before reviewing the specific legislation of the Bills proposed by Senator Hawkins and Congressman Madigan as applicable to the product liability insurance question, I feel I should explain some of the history relative to the insurance coverage and the problems that currently affect the insurance market.

HISTORY

Product liability insurance traditionally has been applied to the covering of liabilities of a manufacturer for the injuries and damages caused by the goods of that manufacturer once they have been sold and relinquished from the ownership of that manufacturer. The general practice has been for the insurance industry to provide general liability insurance policies to manufacturers which include protection for liabilities arising out of general activities in addition to product liability losses. One essential restriction in the coverage applicable to the products liability section of most general liability policies has been that the policy limit which applies to each claim covered by the policy is also restricted to an annual aggregate limit with respect to product liability claims. Consequently, a manufacturer with a policy with a limit of $1,000,000 could have numerous claims arising from the operations hazard, and the insurer could theoretically pay the policy limit over and over again for each of those claims. However, if the claims occurred under the products hazard heading, then the insurer would only pay a maximum of $1,000,000 in any one policy year.

Due to the aggregate limit for the products hazard, it has been the practice for manufacturers to increase their policy limits by securing excess layers of protection by way of excess or "umbrella" liability policies. These policies are traditionally offered by a limited number of insurers as far as vaccines and pharmaceutical products are concerned, and equally their limits are restricted in the annual aggregate for the products liability hazard.

Another important feature of coverage, as it has been arranged in the past, is that claims have been covered on a "losses occurring" basis. That is to say the insurance applicable on the date of the accident or date when the injury occurred is the insurance that responds to the claim. For example, if an accident were to occur in 1980 of which the manufacturer was unaware but received a lawsuit in 1984, it will be the insurance policy applicable in 1980 that would respond to the loss.

This form of coverage has produced numerous practical problems for insurers, and the Insurance Services Organization in the United States is now recommending to its member companies, who in effect comprise most major product liability insurers, that they abandon the "losses occurring" form and change to a "claims-made" form of policy. The "claims-made" policy does not recognize the date of accident or injury as the prerequisite for cover but attaches to claims that are first made against the Insured during its effective policy. Consequently, in looking at the earlier example where the accident occurred in 1980 but the suit was initiated against the manufacturer in 1984, the "claims-made" policy applicable in 1984 would be the coverage that applies.

The provision of "claims-made" forms for manufacturers of vaccines as their only source for product liability protection poses enormous difficulties in the long run. One major disadvantage of the "claims-made" form is that the insurer may cancel cover or refuse to renew thereby leaving the manufacturer totally unprotected for any subsequent losses they may receive even though products may be still out on the market with a potential to cause the manufacturer loss. "Claims-made" forms of policies do incorporate a provision to extend the protection after policy expiry when claims can be notified, but we are frequently seeing this limited to a maximum of a two year period. This will often be regarded as an insufficient period of time by vaccine manufacturers and thereby leaving them inadequately protected for product liability hazard.

THE PROBLEMS OF INSURANCE

The current product liability insurance problems of the American insurance industry, and for that matter the worldwide insurance industry operating in the United States, has been well documented in the newspapers.

There have been many reports in the press pointing to the substantial weakening of various insurers' financial situation in the past year due to heavy claims losses. There have been sufficient difficulties in the insurance marketplace that numerous insurers have either restricted their insurance as far as difficult product hazard risks are concerned or they have totally withdrawn from providing excess and surplus lines policies altogether. The excess surplus lines policies I mentioned are the policies that provide the increased limits so vital to the manufacturers of vaccines.

The question why underwriters lost money on claims can be considered as follows:

(a) The adoption and application of strict liability theories in the U.S. leaves the manufacturers' vaccines extremely vulnerable to plaintiff's in that many defenses are being set aside. For instance, the traditional duty to warn that is incumbent upon manufacturers has been overruled by some courts even though in practice the manufacturer has no contact with the recipient of a vaccine. The manufacturer relies upon the informed physician who has access to complete medical literature including the individual package inserts which detail the necessary warnings.

(b) Many claims are being launched against vaccine manufacturers on the basis of "markets share" theory. By assumption of this theory in other courts across the U.S., the insurers of vaccine manufacturers are now finding that their potential to be exposed to claims is multiplied by the number of other manufacturers in the marketplace who may sustain losses. Hitherto, it was generally felt that the plaintiffs must prove that they were injured by a particular manufacturer's product before an action could succeed.

(c) Another fear of product liability insurers in participating in vaccine producers coverage is that the forms they write will be reinterpreted by the courts. Following the decision in the federal district court for the District of Columbia in the case of Keene Corp., versus Insurance Co. of North America, (an asbestos injury case) underwriters are concerned that their policies that were hitherto written in a form whereby one policy year only would likely be involved with any one claimant, are now being changed by the court to expand cover to pay limits over a period of several years thereby multiplying the exposure to each individual claimant.

THE UNDERWRITING PROCESS

In determining the premium for an individual product risk, or for that matter any other insurance risk, underwriters arrive at a rate through a calculation of two factors/ frequency and severity.

If an underwriter can accurately calculate how frequently injuries will occur in any given number of product sales and coupled with an accurate calculation of the severity of each of those losses, a total claims cost can be calculated.

By applying the total claims costs to the overall market sales of any particular product a rate can be produced which, coupled with a factor for overhead, will produce the insurance premium payable by each of the manufacturers. There are many questions unanswered as to whether particular vaccines can cause reactions and whether those reactions may have occurred regardless of vaccination.

However, the major problem for underwriters at this time is in calculating the severity of any one loss. Due to the complexities of the U.S. judicial system awards can vary both in nature and amount between one jurisdiction and another.

It is my belief that the calculation of the severity of losses is so impossible for underwriters to determine that in many cases this is a primary cause for the lack of coverage being available.

THE CURRENT INSURANCE MARKET CONDITIONS

When a manufacturer is approaching his broker to arrange for a product liability insurance program, there are three considerations that are utmost in the broker's mind:

(i) Policy Coverage

(ii) Market Capacity

(iii) Premium Cost

(i) Looking at policy coverage, I have already explained earlier in this paper the change that insurers are effecting by abandoning the policy form on the "losses occurring" basis and changing to the "claims-made" basis. The "claims made" form of coverage is more restrictive to a manufacturer of vaccines over the "losses occurring" form. If the insurer cancels the ss-made policy or refuses to renew at any time, the manufacturer is completely uninsured for losses that are reported after the cancellation date of the policy. Even if the policy has a provision whereby losses may be reported for an extended period after the expiry date of the claim-made policy, there is a serious potential for claims to be made many years after the manufacturer has sold a product. Consequently, the current insurance market is not offering protection to manufacturers which they may consider satisfactory to protect their corporate assets.

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(ii) Capacity to insure a risk refers to the amount of total insurance coverage that is available in the marketplace to provide total limits to an individual manufacturer. In recent years it has not been unusual for a vaccine manufacturer to maintain overall policy limits in excess of $50,000,000. However, the current demise of the insurance marketplace with the failure or departure of so many major insurers has left numerous manufacturers with totally incomplete insurance programs. In many cases the insured will have to participate himself in various layers of his insurance coverage where insufficient insurance capacity exists to complete those layers, and additionally the overall maximum limits that are available are substantially reduced from the $50,000,000 level and above that I mentioned.

The following major insurers are no longer active in providing product liability insurance coverage to vaccine manufacturers:

TransAmerica Insurance Company
TransAmerica Premier Insurance Company
Northbrook Excess Surplus Insurance Company
Employers Insurance of Wausau
Transit Casualty Company
Midland Insurance Company
Integrity Insurance Company
Royal Insurance Company

This list is not complete but refers to insurers who were hitherto active in writing pharmaceutical and vaccine liability insurance programs. The ultimate effect on the insurance market at this particular time is that a major insurance program can only be undertaken if it is supported by Underwriters at Lloyds and The London Insurance Company Market or insurers represented by the American International Group. The effect of the rapid departure of insurers and the supporting reinsurance market in the United States and overseas has led to an extremely serious capacity shortage in the vaccine of pharmaceutical insurance market.

(iii) As one might expect when the free enterprise system operates to constrict the market supply, the price for what is available rises rapidly. This is particularly true for product liability insurance where premium levels have risen by enormous levels. It is not uncommon to hear of an insured complaining of renewal premiums being offered that are doubled, tripled, quadrupled or many other multiples of the expiring premium cost. Premium costs, although alarming, still take third place in the order of priorities, however.

THE POTENTIAL FOR RECOVERY OF THE INSURANCE MARKET

In my opinion, the basic nature of the insurance industry is to be "reactive" as opposed to "initiative" oriented.

That is to say the insurance industry historically reacts to events after they have occurred and puts its premium prices up after the losses have reached an unacceptable level. In cases where losses suddenly accelerate without warning, this leaves the insurance industry sadly lagging behind, and the problems I have outlined earlier in this paper have compounded insurers' difficulties to the extent that many are recording unprecedented loss levels.

One major source for information concerning the financial well being of the insurance industry are the reports published by AM Best & Company.

ording to information I have read, the 1985 property and casualty company evaluations recently published by Best's show that of the 1,775 U.S. property and casualty insurance companies and reinsurers assessed some 25 percent had their financial rating reduced. In looking at some of the major insurers who have had their financial ratings reduced, many of these were extremely active in the provision of product liability insurance to vaccine and pharmaceutical manufacturers.

Consequently, in considering the problem of securing product liability insurance for vaccine manufacturers, I do not believe that there are many insurers able to participate in any form of vaccine product liability insurance program regardless of legislative changes. Many of the insurers previously active in this type of coverage have had their financial status reduced to the level where many insurance brokers cannot recommend the company as a valid source of protection due to its reduced rating. The recovery of these insurers, therefore, will be a slow and methodical process and can only be encouraged by the potential for profit in the underwriting process.

In the alternate, we can consider insurers who hitherto have never participated in vaccine manufacturers product liability risks. This is an extremely unpredictable field for any broker to calculate in that those insurers who have never participated are likely to have had valid reasons for which the current litigation climate is unlikely to provide relief.

IMMEDIATE CONSIDERATIONS TOWARDS ENCOURAGING PROVISION OF PRODUCT LIABILITY INSURANCE

(A) A limit is needed for any one plaintiff child whereby an insurer can assess the maximum severity of any one individual claim.

(B) Plaintiff legal fees should be inclusive of that maximum limit of liability to any one plaintiff child.

(C) A total pooling of reaction statistics is needed to assess the frequency of loss as accurately as possible.

(D) I do not believe the insurance community will respond to the demands for product liability insurance in the short term. Section 2121 of the Hawkins bill does not clarify the form of coverage that should be provided, i.e., "occurrence basis" or "claims-made" basis form. There is little doubt that the insurance market will no longer provide "occurrence basis" cover in any way.

By permitting the insurance industry to overcome its major difficulty in calculating severity of individual losses, I believe that the underwriting function can work to produce accurate premium costs to meet the relative risks of a supplier to the childhood vaccine market.

QUESTIONS FOR MR. WHITE:

(1) The cost of childhood vaccines has risen dramatically over the last several years. Some have indicated that the major cause of this increase is a large increase in the cost of liability insurance, due to rising and unpredictable claims. Will you please comment on this?

Response

The cost of product liability insurance for vaccine manufacturers has certainly risen very substantially over the last few years and I believe this must be a major component of manufacturers pricing for their products.

The claims experience recorded by Insurers of these vaccines has only been of major significance in those same last few years. In my opinion, it was generally felt that vaccines, having been available and in wide usage for many years did not present a major product hazard to Insurers and the premiums and coverages available up to 1982 reflected that feeling.

Around 1982 the first series of claims began being reported for DPT vaccine and Insurers responded by raising their premiums to meet the anticipated claims costs. As the years have passed so further lawsuits have been issued and the attendant publicity has led to the acceleration in the issuing of further lawsuits. This activity has caused Insurers to withdraw from providing insurance at all, or if they will provide cover then they will do so only with restrictive coverage and very substantial premium costs.

QUESTIONS FOR MR. WHITE

(2) Is the difficulty of obtaining liability coverage for vaccines, and the high cost of that insurance, due mostly to increased claims, or is it also a result of an overall insurance capacity shortage? What parts do each of these factors contribute?

Response

This difficulty of obtaining liability coverage for vaccines is caused by the attendant high financial risk. Heavy settlement potentials and legal costs are perceived to be inevitable to those Insurers providing coverage.

The high financial risk follows directly from the level of claims activity.

The problem of insurance capacity is closely linked to the claims incidence in that Insurers who have suffered heavy losses in the past are in some cases withdrawing from providing cover. However, those Insurers may well be withdrawing due to other problems.

I believe that one could say the difficulty of obtaining cover at all is principally due to the increased claims activity whereas the insurance capacity shortage means that when the coverage can be arranged the amount available is inadequate in my opinion.

QUESTIONS FOR MR. WHITE

(3) In your view, would insurers have problems with a compensation system such as that proposed in H.R. 1780 (the Madigan bill)? Essentially, that system would provide that a hearing panel would determine eligibility and size of award, and then that the respondent(s) would automatically pay the awards. Any disagreement among respondents as to relative liability would be resolved only after claimants have been paid, and would be resolved in a separate proceeding. (The compensation system is based on a no-fault concept.) Please explain.

Response

Insurers' current problems in providing coverage for vaccines arise from their inability to accurately predict frequency and severity of loss.

It is hoped that by virtue of the proposed legislation requiring a far more effective method of recording reactions to the vaccine, that the question of frequency can be accurately answered.

The undertaking of a "no-fault" compensation system with a limit to the amount of compensation that may be given to any one injured person, will give Insurers the opportunity to accurately assess the problem of severity.

Senator HAWKINS. Thank you, Mr. White.

Mr. Hagan.

Mr. HAGAN. Madame Chairman, my name is Charles Hagan, I am vice president and general counsel of American Home Products Corp. Accompanying me is Daniel Shaw, M.D., vice president for medical affairs of Wyeth Laboratories Division. We appreciate the opportunity to appear before you today.

Currently, Wyeth sells to the health care profession only two vaccines that are used in childhood immunization. These are diphtheria and tetanus, pediatric and adult. We continue to manufacture DTP vaccine for Lederle to sell and distribute under an indemnity agreement.

Wyeth discontinued the general sale and distribution of DTP vaccine last June 13, and we notified FDA, CDC, and others of that decision, and of the reasons for this action. We withdrew from the market because of the substantial liability exposure, cost of litigation, and the difficulty of continuing to obtain adequate liability insurance.

Turning now to the two bills before us today, both of these bills include findings which recognize both the need to provide fair compensation for vaccine-related injuries, with regard to mandatory childhood vaccines, and the need to assure continued availability of an adequate supply of such vaccines.

We, of course, subscribe to both of these goals, but as to the DTP vaccine, achievement of both goals through legislation will be most difficult.

In our view, H.R. 7180 is more likely to achieve both goals than is S. 827, especially with respect to assuring adequate supplies of that vaccine. S. 827 allows tort litigation as an alternative to compensation and places no limit on recovery for economic loss under the compensation alternative.

As you undoubtedly know, within the last 2 years, there has been a great increase in the number of tort suits involving the DTP vaccine, primarily claiming permanent neurological injury.

A recent fact sheet, published by the American Academy of Pediatrics, estimates an annual incidence of 50 cases of permanent neurological injury associated with this vaccine.

Under the tort system, recoveries for such injuries can be huge. Within this past year, we are aware of two jury verdicts, each in excess of $20 million, in cases involving such injuries to children, although neither of those cases happen to involve the DTP vaccine.

Madame Chairman, you mentioned before, with respect to the Lederle price increase, that that increase might amount to as much as $22 million a year. This experience teaches us that even one jury verdict, in the approximately 200 DTP suits now pending against the three of us, could take away not only the profit of that increase, but the total amount of the increase.

Trials of suits involving this DTP vaccine are scheduled for this fall. Should similar verdicts occur, one would have to question whether S. 827 would assure continued availability of that vaccine, since it leaves the tort law intact.

In recent hearings before Senator Danforth's subcommittee, witness after witness testified as to the problems with the tort system. As a consequence of these problems, the availability of liability insurance has been sharply curtailed, as we have just heard, and the cost of what is available has greatly increased.

S. 827 does recognize the existing insurance problem, and part B authorizes the Secretary of HHS to implement development of an insurance pool and reinsurance coverage, under certain circumstances.

We commend the committee for recognizing and attempting to deal with this problem. Since our company no longer distributes the DTP vaccine generally, except to Lederle, which indemnifies us, our interest in this legislation is not as great as that of Lederle and Connaught because injuries are rare with the two childhood vaccines we do continue to market generally, and we have no product liability suits involving them.

We appreciate the opportunity to testify today, and we applaud the willingness of this committee to attempt to find a legislative solution to these difficult problems.

[The prepared statement of Mr. Hagan and responses to questions by the American Home Products Corp. follow:]

Statement

Of

Charles F. Hagan

Vice President

American Home Products Corporation

And

Daniel L. Shaw, M.D.

Vice President for Medical Affairs

Wyeth Laboratories Division

On

"Childhood Immunization: Problems and Options"

Before the

Senate Committee on Labor and Human Resources

July 18, 1985

My name is Charles F. Hagan and I am a Vice President and General Counsel of American Home Products Corporation. Accompanying me is Daniel L. Shaw, M.D., Vice President for Medical Affairs of our Wyeth Laboratories division. In this brief statement, we will attempt to cover the matters referred to in the Chairman's letter to us of July 3, but we will leave a detailed discussion of S 827 and HR 1780 to the other two vaccine manufacturers who are testifying today since their interest in such legislation is greater than ours.

Currently Wyeth sells to the health care profession only two vaccines that are used in childhood immunization programs. These are Diphtheria and Tetanus Toxoids Adsorbed (Pediatric) and Diphtheria and Tetanus Toxoids (Adult); the latter being used in children 7 years of age or older. We continue to manufacture DPT Vaccine for Lederle to sell and distribute under an indemnity agreement.

In regard to selling prices for these two vaccines they have been relatively stable over the past five years with some escalation in the past two years. We have a catalogue price for our trade customers, physicians, hospitals, etc. and bid prices to state and local governments. For 1980, the catalogue price for D.T. Pediatric ranged from $3.75 to $4.10 for a 10-dose package. This price increased to $4.72 in 1981, $5.19 in 1982, and was priced at $6.28 in 1983 and 1984. The current 1985 selling price is $6.28 per 10-dose vial. Bid prices to state and local governments have consistently ranged from $1.75 to $3.30 over the same 5 year period.

Prices for Tetanus and Diphtheria Toxoids Adsorbed (Adult) were priced identically to the Pediatric preparation over the same 5 year period.

Wyeth distributed a total of approximately 145,500 ten dose vials and 100,000 packages of 10 single dose units of D.T. Pediatric over the past 5 years. This is equivalent to approximately 2,455,000 doses. The current rate of distribution for the last full year is approximately 565,000 doses. Ir [illegible] ie same 5 year period, Wyeth distributed 785,800 10-dose units of D. [illegible] ult, equivalent to 7,858,000 doses. The current rate of distribution for the last full year is approximately 3,800,000 doses. This yearly rate increased significantly in 1984 for the adult preparation, whereas an increase in rate began in 1982 for the pediatric dosage form.

Wyeth discontinued the general sale and distribution of DPT Vaccine June 13, 1984, and notified FDA, CDC and others of that decision and of the reasons for this action. We withdrew from the market because of substantial liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance.

In regard to selling prices for DPT prior to leaving the market, they ranged from $4.05 per 15 dose vial in 1980 to $20.00 per 15 dose vial in June of 1984. These were the prices to the private sector. For state and local governments, bid prices ranged from $1.98 - $2.25 in 1980 to $9.50 - $38.00 in 1984 when we left the market.

Wyeth distributed approximately 33,875,000 doses of DPT from 1980 through June of 1984. In 1983, our last full year of sales, we distributed 7,412,350 doses of DPT. Since discontinuing general sale and distribution of DPT, we have supplied Lederle with 2,887,500 doses in 1984. We will supply them with 8,400,000 doses in 1985 and 9,450,000 during the first quarter of 1986.

In the area of vaccine research, Wyeth expended in 1984 approximately one-half million dollars toward the development of a DPT Vaccine with an accellular pertussis component licensed from Takeda in Japan. Sums in excess of 3 million dollars were also expended by Wyeth during 1984 for research on the development of new vaccines.

Turning now to S 827 and HR 1780, both of these bills include findings which recognize both the need to provide fair compensation for vaccine-related injuries, with regard to mandatory childhood vaccines, and the need to assure continued availability of an adequate supply of such vaccines. We, of course, subscribe to both of those goals but, as to the DPT Vaccine, achievement of both goals through legislation will be difficult.

In our view, HR 1780 is more likely to achieve both goals than is S 827, especially with respect to assuring adequate supply of that vaccine. S 827 allows tort litigation, as an alternative to compensation, and places no limit on recovery for economic loss under the compensation alternative.

As you undoubtedly know, within the past two years there has been a great increase in the number of tort suits involving the DPT Vaccine, primarily claiming permanent neurological injury. A recent fact sheet published by the American Academy of Pediatrics estimates an annual incidence of fifty cases of permanent neurological injury associated with this vaccine.

Under the tort system, recoveries for such injuries can be huge. Within this past year, we are aware of two jury verdicts each in excess of $20 million in cases involving such injuries to children, although neither involved the DPT Vaccine. Trials of suits involving the DPT Vaccine are scheduled for this fall. Should similar jury verdicts occur one would have to question whether S 827 would assure continued availability of that vaccine since it leaves the tort law intact.

As you undoubtedly know, in recent hearings before the Consumer Subcommittee of the Senate Commerce Committee, witness after witness testified as to the problems with the tort system. As a consequence of these problems, the availability of liability insurance has been sharply curtailed, and the cost of what is available has greatly increased. S 827 does recognize the existing insurance problem and Part B authorizes the Secretary of HHS to implement development of an insurance pool and reinsurance coverage, under certain circumstances. We commend the Committee for recognizing and attempting to deal with this problem.

Since our company no longer distributes the DPT Vaccine, except to Lederle Laboratories which indemnifies us, our interest in this legislation is not as great as that of Lederle and Connaught because injuries are rare with the two childhood vaccines that we continue to market, and we have no product liability suits involving them.

We appreciate the opportunity to testify today, and we applaud the willingness of this Committee to attempt to find a legislative solution to these problems.

Responses by American Home Products Corporation
To Questions On Vaccines

(1) If Congress were unable to pass legislation that addresses the problems identified in your testimony, what is the possibility that you will not remain in the vaccine business?

1. At the present time, we intend to continue manufacturing and marketing vaccines, including DT (Pediatric) and Td vaccines for children, and to pursue our active basic research program for other needed vaccines. However, if the litigation and insurance situation should worsen significantly as it relates to vaccines other than DTP, we would have to reconsider our position both as to marketing and research. At the present time we have no plan to reenter the DTP market.

(2) Do you believe that the DTP vaccine you are currently manufacturing is the safest possible product? How do you respond to allegations that industry is not doing all that can be done to improve vaccines, particularly the pertussis vaccine?

2. We feel that the current DTP vaccine is as safe a vaccine, in terms of serious side effects, as is possible compatible with current scientific knowledge and testing capabilities.

(3) What is your problem with the solution posed to the vaccine compensation issue in S. 827? Why can't you support this approach?

3. The principal problem with S.827 is that it leaves the tort system intact, as an alternate to compensation. As mentioned in our testimony, in recent hearings before the Consumer Subcommittee of the Senate Commerce Committee, witness after witness testified as to severe problems with the tort system. As a consequence of these problems, the availability of liability insurance has been sharply curtailed, and the cost of what is available has sharply increased, as shown by our answer to questions 6 and 8.

(4) Do you believe consumers should be allowed to sue on the grounds of gross negligence wherever such grounds exist?

4. The Department of HHS has established standards for all childhood vaccines. These standards encompass all aspects of the manufacturing, testing, packaging and labeling of the immunizing agent, which vaccine is then also sent to that federal agency for testing before it is released for use in humans. If a manufacturer releases a batch which fails to meet those standards and that failure causes injury, the manufacturer should be subject to suit. However, all vaccines and other immunizing agents have unavoidable side effects, even when they full comply with such standards. In our view, manufacturers should not be subject to suit for such side effects. The public benefits from availability of such vaccines and, since the vaccines covered by S.827 are required by most states and recommended for use by the federal government, the public should compensate those who suffer such side effects.

(5) What is the cause of the vaccine shortage we have been experiencing lately?

5. To our knowledge there is no present vaccine shortage. A reported DTP shortage earlier this year has apparently abated.

(6) There has been a great deal of attention focused on the fact that manufacturers of the DPT vaccine have been driven from the market because they can't get insurance. Could you elaborate on this?

6. For the year beginning July 1, 1985, our company has been able to purchase only about 15% of the product liability insurance which we have had in many previous years, and a number of our current policies exclude the DTP vaccine.

Will you please provide the Committee with the following information:

(7) A list of all lawsuits filed against you during the last five years in connection with DPT vaccine.

(8) A list of each of your insurance companies for each of the last five years and a statement of the coverage provided and the premiums paid. Also, please provide a list of claims paid under these policies.

7. From January 1, 1980, to present approximately 100 DTP lawsuits have been filed against Wyeth. Approximately 91 such suits are pending.

8. Attached as Appendices A through F* are lists of insurance companies providing liability coverage to our company, broken down by layers of coverage for the past five years. The total annual premiums paid for such insurance for each of these years is also stated. During these five years no claims against us for vaccine injuries have been paid by any of these insurance companies, although in 1984 a former carrier, Liberty Mutual, paid $1,350,000 to settle a DTP suit.

(9) An organization called Advocates for a Safe Vaccine, and the parents organization, "DPT," have provided us with a report containing information, including documents obtained through discovery, regarding what is alleged to be the failure of the industry to pursue development of a safe pertussis vaccine, and the industry's lack of forthrightness about the safety of the vaccine. If you do not have a copy of this report, entitled "D.T.P. Vaccine: Interim Report," the Committee can provide it to you. Will you please respond to the report, either specifically, point by point, or at least in general. Can you at the miniumum respond to the overall thrust of the report, which seems to be (a) the industry has been well aware for some time of the need to develop a safer vaccine and has had the knowledge and techniques to do this, but has not done so; and (b) the current test for toxicity is recognized to be outdated and inaccurate, yet industry has continued to use this test, thus marketing a product with uncertain toxicity.

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*Because of the volume of these materials, they were retained in the Committee files.

9(a) We believe our answers to questions 2 and 12[**] are responsive to subsection (a).

9(b). We assume this question relates to the mouse weight-gain test. Wyeth performs the mouse weight-gain test on pertussis vaccine in order to ascertain whether it has completed the process of detoxification-with-aging in the presence of thimerosal. This toxicity test, mandated by FDA regulations for performance on the bulk DTP, is designed to detect excess amounts of toxins in the pertussis known as endotoxin, dermonecrotic toxin (DNT) and pertussis toxin (PT). Some unknown amount of detoxified PT, however, may be necessary in a pertussis vaccine in order to induce immunity. There is scientific evidence and opinion that the mouse-gain test correlates with the clinical reactivity (local and febrile reactions) of DTP.

Other toxicity tests for pertussis vaccine have been explored, but none have been accepted for routine testing except the HSF titration in Holland. In a collaboratory study in the United States in the 1960's, twelve laboratories performed one or more of 11 different tests which had been purported to test the toxicity of pertussis vaccine. The results indicated that none of the other tests were superior to the mouse weight-gain test. The mouse toxicity test is recommended by the WHO Requirements for Pertussis Vaccine (World Health Organization, 1964). It is widely accepted in the world as the control test for freedom from toxicity of pertussis vaccine.

[**] Because the technical information contained in these responses is matter involved in pending litigation, it was retained in the Committee files.

It is unknown whether DTP contains a "neuro-toxin" causative of serious neurologic injury, and, if so, its composition, location and function in the B. pertussis cell. Therefore, at present no test for an unknown "neuro-toxin" can be devised and correlated with either its presence and quantity in pertussis vaccine or its effect on humans if indeed there is a causal relationship between administration of vaccine and occurrence of serious neurologic side effects in humans.

(10) What are the prospects that your vaccine research will produce a better pertussis vaccine in the near future?

10. The prospects are dim for the U.S. introduction of a new pertussis vaccine in the near future.

(11) How much do you spend on research on a safer pertussis vaccine? What percentage is this of your company's profits? What percentage is it of your profits from the sale of the DTP vaccine?

11. During 1984 Wyeth expended about a half million dollars on development of a DTP vaccine with an acellular component licensed from Takeda in Japan.

(12) Will you please respond to reports that you had, a few years ago, a formula for a safer vaccine, but chose not to pursue marketing that product?[***]

[***] Because of pending litigation in which this information is involved, the response was retained in the Committee files.

(13) You manufacture DTP and sell it to Lederle, which distributes it and assumes the liability. What is the possibility that you will, in the near future, be able to re-enter the market fully? Does this eventuality hinge on the passage of legislation?

13. At this time we have no plan to reenter the DTP market.

Senator HAWKINS. There is a vote on, and in the interest of having this Senator participate, I will submit my questions to all of you in writing also. I have them here. I will dismiss this panel and call the last panel to the table while I am voting, comprised of representatives of medical and health professional groups, Dr. Alan Nelson, Dr. Martin Smith, and Dr. Bailus Walker.

[Whereupon, a brief recess was taken.]

Senator HAWKINS. We will come to order, please. This last panel is made up of representatives of medical and health professional groups, which are very concerned about this issue. They are Dr. Alan Nelson of the American Medical Association; Dr. Martin Smith of the American Academy of Pediatrics, and Dr. Bailus Walker of the Association of State and Territorial Health Officials.

We are expecting another vote shortly, so I will make the same request to all of you, that you submit your full statements for the record and try to summarize your testimony in 5 minutes.

Dr. Smith, welcome; we will call on you first.

STATEMENTS OF DR. MARTIN H. SMITH, PRESIDENT, AMERICAN ACADEMY OF PEDIATRICS; DR. ALAN R. NELSON, VICE CHAIRMAN, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; AND DR. BAILUS WALKER, MASSACHUSETTS COMMISSIONER OF PUBLIC HEALTH, ON BEHALF OF THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Dr. SMITH. Madame Chairman, the academy has submitted its written testimony in full, and I will try to summarize it in a brief statement.

I am Dr. Martin H. Smith, a pediatrician in private practice and Vice President of the American Academy of Pediatrics, here today to speak in support of Senate bill 827.

On behalf of the Academy, I want to publicly thank those Senators and their staff members who have spent their time and energies in the development and introduction of this legislation in an effort to solve a distressing public health problem.

It has been eight years now since the Academy first issued its policy statement supporting the creation of a Federal program of compensation for vaccine-related injuries occurring in the Childhood Immunization Program.

Since that time, we have had the benefit of congressional hearings, meetings with interested parties, many reviews, and rewrites. S. 827 incorporates the necessary revisions and fine tunings from these tedious processes, and deserves our full attention and support for its passage.

Let me make clear that our objective here is nothing more nor less than simple justice for the children of this country. While we can take great pride in the successes of our Childhood Immunization Program, a few children each year are unavoidably injured by their mandated participation in this program. Society is the beneficiary of these mandated programs and society should be responsible for providing adequate and expeditious compensation.

At present, compensation is available only in a slow and uncertain court process, in which there must be an attempt to prove fault; in fact, in most instances, there has been no fault in the production or in the administration of the vaccines.

We believe that through these past 8 years, these concepts have won the acceptance of the American public and of the Congress. There remains now only the necessity for devising the best system for accomplishing the goal of compensation to any injured child, equitably and promptly.

At the same time, we must be concerned that we develop a climate that allows additional and competitive vaccine producers back into the market and encourages the innovative development of new vaccines.

We are still in the infancy of the tremendous potential of the use of vaccines, but no incentive for further development exists in the present litigious atmosphere of this field. We cannot let this opportunity pass without raising again the plea for improved vaccines. All of the existing vaccines can be improved, especially the pertussis vaccine.

The Academy has pleaded repeatedly for priority funding for research on vaccines. The bill under consideration today creates this essential mandate.

In the past year, we have been to the very brink of a disaster in which all immunizing would have had to be stopped. We reached the point where the required seven common childhood diseases vaccines were being produced by only two vaccine producers.

Now we have gone back from the brink, with three DTP producers, one polio and one MMR—measles, mumps, and rubella—producers being in the market. We cannot be comfortable, however, since their ability to continue is a day-to-day determination, made by their liability insurers, as we have heard this morning. We could pass over that brink at any time; and if that occurs, we have no alternative but to resume having disease.

These are diseases that are preventable by the available medical resources. But these are resources that will continue to be available only if this Congress asserts its responsibility to avoid the crisis.

We may be able now to provide better supportive treatment than we could 50 or 60 years ago for children suffering from one of these childhood diseases, but we must be conscious of the fact that we still have no specific antibotic for any one of these childhood diseases.

We have been through the days of 250,000 cases of diphtheria per year, with 15,000 deaths; 1 million cases of measles, with 7,000 deaths; 250,000 cases of pertussis, with 7,500 deaths; 25,000 cases of polio, with 3,000 deaths, and most of the survivors showing residual paralysis.

It is insane for this country to flirt with a return to anything resembling these figures. If it is allowed to happen, the public will rise up in righteous and justified indignation.

We have tried, in the Academy, to look at the incidence of these diseases in the past, look at the years that they occurred, and look at what would be projected for future years, or now, if we had a lapse in vaccine production and/or a lapse in the administration of vaccines.

What you see here is extrapolation of the peak years of occurrence of disease in the past, extrapolating those figures to the present-day population, and you can look at the horrendous toll that these diseases would take, one by one: polio, diphtheria, whooping cough, measles, and so on.

Now, if I can depart just for a moment, I want to make a plea that while we have hearings and debate ongoing that are necessary on this subject, these must occur without running the risk of the same scenario taking place in this country that has taken place in Japan and in Great Britian. We must have these occur without the loss of public confidence in the immunization program or the use of the products currently available.

I am sorry that I didn't bring with me an impressive table from the July 1985 issue of Pediatrics, the journal of the American Academy of Pediatrics. On page 47 there is a list from the World Health Organization, from 1983, for three diseases in the countries that are less fortunate than we are. They listed the deaths in those countries due to whooping cough, tetanus and measles. Almost 5 million children died in 1983 in those countries from the failure to use the products that we have. We cannot let ourselves fall into this sort of circumstance in the midst of this debate.

From the beginning of our advocacy of a compensation system, a prime concern has been to ensure the prompt and equitable compensation of those who are truly injured, but at the same time sort out those temporally associated events as completely as possible if they could mimic vaccine reactions.

The table of injuries, appearing in this legisiation, is our attempt to serve that purpose. It represents the advice of Academy experts as to the types of serious reactions possible from each vaccine and the limits of time that can be reasonably allowed for the appearance of these reactions after each dose.

It may never be possible to perfectly sort these claims, but we maintain that this type of mechanism can bring us closer to the ideal judgment of the claims, as they will arise.

We hope that this type of table can be included in the legislation, rather than wait for the indeterminate time of rulemaking. The legislation provides a mechanism for modification of the table as experience creates the need.

There have been other legislative proposals introduced and there will be additional proposals submitted. The academy has tried to judge these proposals according to two criteria: First, does it provide a better and more prompt form of justice for children than is presently available. This is the first and the most important criterion.

Second, does it create an improved environment that will allow continual production of vaccine, competitive production of vaccine and encourage new vaccine development.

We have had access to all of the proposals at their developmental stages and it has been our considered opinion that only S. 827 measures up to both of these criteria.

The Academy presents the testimony here today in our customary role, that of representing the interest of children, our patients. In their behalf, we plead or prompt action on this legislation.

If this situation seems any less urgent now, we must not fall into that false complacency. If it is possible to devise a better form of justice, that in itself is an urgent matter.

Thank you for this opportunity.

[The prepared statement of Dr. Smith and responses to questions for the record follow:]

American Academy of Pediatrics

TESTIMONY

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

ON

S.827, THE "NATIONAL CHILDHOOD VACCINE INJURY

COMPENSATION ACT OF 1985"

PRESENTED BY

Martin H. Smith, M.D., F.A.A.P.

JULY 18, 1985

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I am Dr. Martin Smith, a pediatrician in private practice and vice president of the American Academy of Pediatrics, here today to speak in support of Senate Bill 827. On behalf of the Academy, I want to publicly thank the senators and their staff members who have spent time and effort in the development and introduction of this legislation to solve a distressing public health problem.

It has been eight years since the Academy first published its policy statement in this regard. Let me make clear that our objective is nothing more nor less than simple justice for the children of this country. Since laws are in place for the public good which require that children be immunized before entering school, and since it is inevitable that a few children will be injured as a result of compliance with these laws, then it only follows that the public should be responsible for providing adequate and expeditious compensation.

At present, there is no recourse for the injured child except to pursue compensation through the courts. Here an attempt must be made to establish fault on the part of the vaccine manufacturer or the one administering the vaccine, when, in fact, there is most often no fault in either party. If provision of a financial settlement depends on proving fault, it is very possible that one truly injured will be denied any compensation whatsoever. The tort process is slow, tedious and difficult to pursue for families, and it is an expensive undertaking.

Children are not necessarily well served by our judicial system. It can take six to eight years for a lawsuit to reach its conclusion and then, if a settlement is reached, a large part of the sum is consumed by the legal process. During this [illegible] expenses for the injured child are continually mounting and, in most instances, these expenses are considerable.

Every year approximately 3,000,000 children are born in this country. For their basic immunizing, those 3,000,000 will each require three doses of DTP and two doses of oral polio vaccine. At 18 months they require a booster dose of each of these vaccines and again, at school entry, a booster dose of DTP and oral polio. This results in a minimum of 15,000,000 doses of DTP and 8,000,000 doses of polio that are given each year. Even with proper administration and use of the best vaccine products available today, we can expect a case of polio-like disease to result out of each 5,000,000 doses of polio vaccine and a serious, permanent neurological disorder to result from every 310,000 doses of DTP. Thus, with the annual doses of DTP and polio administered, there will be at least two cases of paralytic disease and at least 50 permanent neurologic injuries that follow. These occur through no fault of the provider or the producer of the vaccine. This is an annual year-in and year-out toll that is inevitable if we are to maintain an immunized population.

This country has never enjoyed such freedom from preventable childhood diseases. The history of the dreaded childhood diseases prior to the days when our present vaccines became available clearly illustrates their terrible toll. We cannot go back to those days either out of concern for the few injuries that occur today or because of loss of U.S. suppliers of vaccine. While we continue to press hard for continued research to produce better vaccines in the future that will be free of reactions, we still have no specific treatment for any one of the childhood diseases. This nation's commitment to provide all children the maximum protection from preventable childhood diseases must not waiver.

of all medical procedures, the full utilization of a complete immunization program is the easiest to document on a cost-effectiveness basis. Yet, the Academy must express grave concern that we could be at a crisis point at any time, either with loss of supply of vaccine or with such an escalation in cost that it could result in a shattering of our excellent program. Outside of developing a compensation program for children, our concerns for supply and cost of vaccine and the ability to continue a full immunization program have been the major reasons for the tremendous interest of the Academy in the subject.

The constantly increasing burden of large vaccine injury settlements has had serious adverse effects on vaccine supply. The number of vaccine producers has been sharply reduced in recent years and the cost of vaccine has increased dramatically. Both of these effects can be related in part to the burden of liability the vaccine producers are carrying currently. The result is that we now have only one source of supply for polio, measles, German measles and mumps vaccine, and only three sources of supply for DTP vaccine. This is certainly not a competitive situation, which Americans would typically favor, and it does not give one a sense of a secure supply.

This country was indeed on the brink of disaster this year when one of the manufacturers of DTP vaccine dropped out of the market, another stopped distributing DTP and a bad batch of DTP was recalled from the sole remaining company. This country experienced a shortage of DTP vaccine, and in an effort to conserve supplies to protect the youngest and most vulnerable children, the booster shots for pre-schoolers were delayed. For some states, disaster had already struck. Vermont, for example, was assigned top priority during the national shortage, because it had an extremely large number of cases of pertussis, two of which caused the death of young children.

While we experienced no disruption in supply in measles, mumps and rubella vaccine, we have seen measles outbreaks in at least six states. Three deaths occurred at an Illinois college. The high attack rate (15.9 percent) on this college campus was undoubtedly due to the students' very low immunization levels. This outbreak clearly illustrates the potential severity of measles and the rapidity of spread in an unvaccinated population.

Hence, an immediate concern must be the absence of adequate federal safeguards to avert what would be a national health crisis if any one of the producers (or distributors) of our childhood vaccines were unable to continue to provide the product. Aside from the obvious threat of escalating liability costs, manufacturing difficulties or even natural disasters could destroy our nation's vaccine supply.

The Academy certainly shares the concerns of Congress over the costs of such a program. We commissioned our own cost study which is a part of last year's hearing record. Due to the various options now before Congress, we have not revised that study to incorporate the considerable cost savings in S.827. Many variables still exist and must be worked out by this Committee. One key factor to keep in mind is that all estimates to date are for the total cost of the program. Not all of these costs are new costs. These ongoing costs are considerable as evidenced by the rapidly escalating prices of the vaccine products. Over the past year alone, the cost of MMR purchased, in bulk, by the federal government, increased 26.9 percent, polio 10 percent and DTP 10 percent (up 300 percent over the past two years). CDC cost estimates provide for a 25 percent increase in MMR, a 10 percent increase in polio and a 10 percent increase in DTP for fiscal 1986. Costs to private physicians are even more dramatic. Since 1983, private physician costs for polio have increased over 90 percent (from $2.80 a dose to $5.33 a dose), DTP by over 500 percent (from $.50 a dose to $3.08 a dose) and MMR by almost 300 percent (from $5.16 a dose to $14.88 a dose). A significant percentage of these increases is due to the liability insurance costs to the manufacturer. The surcharge provision in S.827 is designed to help offset the costs of the compensation system.

A cost-related issue is the kind of injuries that will be covered under the legislation. With the assistance of our own pediatric epidemiologists and neurologists, and with the concurrence of the parents' group, S.827 contains a scientifically defensible and equitable table of compensable events. Compensation would be awarded only for major adverse reactions which have, in the past, been demonstrated to have a causal connection to the particular vaccine in issue. The proposed bill specifies the adverse reactions to be covered and the time frame under which these reactions must occur. Provisions are made for the Secretary DHHS to modify this list based on new medical and scientific evidence or findings.

We have spent many hours debating some of the features that have gone into this legislation. It would be well to mention some that required particular consideration and offer some explanation.

#1: The legislation provides for an optional system. It is arguable that a mandatory system could be more easily administered and the cost estimates could be developed more precisely. However, we had great concern whether the enactment of such a mandatory system would hold up under the tests of constitutionality. It certainly would be argued that a mandatory system would deprive individuals of their access to court if that access were desired.

#2: The legislation requires a prompt settlement of claims. This is fundamental to any improved system.

#3: The law mandates an obligation to pursue improved vaccines. This obligation arises now only through competition in the marketplace and no competition exists for most vaccines.

#4: The legislation requires the reporting of reactions rather than the present voluntary reporting. It is hoped that mandatory reporting would develop more exact data of the actual occurrence of reactions.

#5. The legislation makes provision for realistic awards. It is expected that with the awards being realistic, and with the system giving prompt settlements, there would be an incentive to accept the option of going into this system for settlement.

#6: The legislation requires better parent information. This provision is key to assuring public confidence in the immunization program. Examples of materials developed by the Academy in this regard are attached.

While we are asking Congress to assume a new responsibility in providing a system for compensation in these special instances, it is not an untested idea. Variations on this idea have functioned for several years in most of the Western European nations and in Japan. Many of these nations are less capable of extending these benefits to their citizens than is this great country.

There has been other legislation introduced dealing with the problem of vaccine compensation, and there will be additional legislation proposed. The Academy has tried to judge all these proposals according to two criteria:

I Does it provide a better and prompter form of justice for children than is presently available?

II Does it create an improved environment that will allow continued production of vaccine and competitive production of vaccine, and will encourage new vaccine development?

We have had access to all of the proposals in their developmental stages. It has been our considered judgment that only S.827 measures up to both of these criteria.

The time is now for action. We cannot delay. The problem is real and it is pressing. The cost of a resolution is not exorbitant. The cost of continued neglect can be much greater.

DTP Vaccine Information Sheet

Date

Your child has just received the (1st, 2nd, 3rd, 4th, 5th) shot of the DTP (diphtheria-tetanus-pertussis) vaccine.

The following conditions are *usual* reactions you may expect your child to have:

☐ fever

☐ irritability for up to 2 days

☐ some soreness and swelling in the injection site

The following reactions are less common. If your child displays *any* of them, please call my office:

☐ high-pitched persistent crying for more than three hours

☐ excessive sleepiness or difficulty in rousing the infant

☐ limpness or paleness

☐ temperature of 103° or higher

☐ convulsion

Most vaccine reactions are not significant and will disappear a few days after your child has been vaccinated. Occasionally, however, a problem is identified after a DTP shot is given. Please call me to report any reaction you suspect is serious so your child can be examined and treated if necessary.

Dr. Name

Address

Telephone

American
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Pediatrics

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August 1, 1985

Honorable Orrin G. Hatch
Chairman, Committee on Labor and
Human Resources
United States Senate
Washington, D.C. 20510

Dear Senator Hatch:

I am pleased to respond to the questions submitted to me for the record at your hearing on July 18, 1985 on "Childhood Immunization: Problems and Options."

I commend you for your leadership in this regard.

Sincerely yours,

Martin H. Smith

Martin H. Smith, M.D.
Vice-President

MHS/lck

(1) The Administration tells us that including a table of compensable events in legislation severely limits flexibility and the ability to change the list as scientific and medical information changes. Can you comment on this?

Much to the contrary. The Table of Compensable events was developed by Academy experts, both in infectious diseases and neurology, and approved by the parents' group, as a scientifically sound listing of recognized reactions to the pediatric vaccines. It is included within the legislation to enable immediate implementation of the compensation program rather than delay it by the lengthy and tedious process of rulemaking. The Table is not yet set in concrete and should be reviewed by the Administration's own experts. The bill provides for modifications of the Table as more information becomes known. There is no intention here of interfering with needed changes or modification.

(2) It is your view that pediatricians are more vigilant than they were a few years ago with respect to talking with patients about vaccine contraindications and side effects?

I don't know if "vigilant" is the appropriate word here, in that most pediatricians have always discussed the childhood immunization program with parents. In my travels around the country, I am finding, however, that pediatricians are spending more time discussing vaccine contraindications and possible side effects and that a majority of pediatricians are requiring parents to sign informed consent forms.

(3) What do you estimate is the distribution of your information materials? Are all pediatricians distributing or displaying these things? How are you keeping track of the success of this effort?

The Academy's informational materials have been circulated to our 28,000 members, all state medical societies and all state health departments. Notices of their availability are now running in various health-related newsletters. No evaluation of the use of these materials is yet available, but the number of requests for these materials increases daily. I should point out that these materials are literally "hot off the press" so our feedback is limited at this time.

(4) Do you believe that a "no-fault" compensation system, such as that set up in S.827, essentially gets negligent physicians "off the hook"?

Let me assure this Committee that there is no intention here to get negligent physicians "off the hook." The "no-fault" system in S.827 is optional; a parent may in fact go to court and sue negligent physicians. The "no-fault" system simply recognizes the fact that a small number of injuries are unavoidable. It is the most fair and equitable system for parents of injured children.

(5) From your perspective as practicing physicians and as individuals with an obvious interest in this issue and obvious considerable knowledge about what is going on in your profession, would you agree with the parents' groups agrument to the effect that there is great underestimation of the incidence of adverse reactions to vaccines?

We simply do not know who is right or wrong in the argument. Most probably not all adverse reactions to vaccines are reported in the United States. Likewise, some reactions may be reported that are not related to the vaccines. We need a better accounting of true adverse reactions and S.827 sets up the mechanism by which such an accounting can be made.

Senator HAWKINS. Thank you, Dr. Smith. Dr. Nelson.

Dr. NELSON. Thank you, Madame Chairman.

My name is Alan Nelson, I am an internist in private practice in Salt Lake City, and I'm vice chairman of the American Medical Association's board of trustees. With me today is Mr. Harry Peterson, the director of the AMA's division of legislative activities.

The American Medical Association is pleased to discuss the issues surrounding childhood immunization in this country. We have the same goals; we differ only in our approach to the solution to reaching those goals.

In our view, it is critical to assure a steady, adequate supply of needed childhood vaccines in a market characterized by an unstable court liability climate, an instability which already has caused one disruption in vaccine supply.

We are also deeply concerned about the need to provide for fair and adequate compensation to those injured as a result of mandated pediatric vaccines.

Finally, we are committed to making immunization as safe as possible.

In recent times, there has been a supply disruption that has resulted in short-term shortages, rationing, and postponement of needed, important vaccine inoculations. The results of the inherent structural instability of the vaccine market could lead to more serious long-term shortages that would impact on our ability to maintain this Nation's excellent immunization effort.

The CDC has withdrawn its rationing recommendation, and DTP is once more in adequate supply due to Connaught's reentry into the market after obtaining liability protection. But concerns about possibly unsuccessful efforts by Lederle to seek satisfactory insurance protection were allayed only when that company announced that it had obtained liability protection.

We have heard today that this remission may be short lived. The next crisis may not be resolved as quickly and could have serious impacts on childhood immunization levels. This is especially true in considering the number of vaccines that are available only from one source.

We are concerned also about the potential for epidemics because of decreased immunization rates, resulting from fearfulness of vaccine safety. We share Dr. Smith's concern that we may have epidemics in this country as immunization rates drop because of uncertainty about the real cost benefits—the cost and benefits of immunization.

Madame Chairman, with the latest emergency behind us, now is a good time to consider carefully legislation to avert the next, possibly more serious vaccine crisis, and to address the need to provide fair and equitable compensation for those injured due to a mandated pediatric vaccine.

We urge this committee to continue to maintain vaccine-injury legislation as a major priority for this session of Congress.

Two bills have been introduced in this Congress dealing with vaccine-injury compensation, your own bill, S. 827, and H.R. 1780.

S. 827 is a modified version of a bill in the last Congress and would establish a Federal vaccine-injury compensation program. The principal differences between S. 827 and its predecessor in the

98th Congress include narrowing the list of compensable injuries to only the more severe reactions, protecting any manufacturer from liability solely due to its failure to provide a direct warning to the injured party of potential dangers, and establishing a mechanism for HHS-coordinated insurance pools and reinsurance.

The Government program, funded by a surcharge on the vaccine, continues to be an option to the existing tort system, not the exclusive remedy.

We applaud your efforts, Senator Hawkins, to provide solutions to these important problems. Your revised bill contains many improvements over your earlier version. However, in spite of the number of improvements in the revised version of this legislation, the AMA cannot support S. 827, in its entirety, because of certain fundamental provisions contained in the bill with which we must disagree.

A major feature of S. 827 is the establishment of the Federal Compensation Program as an alternative to the traditional tort remedy, rather than being the sole source of compensation for vaccine-related injuries.

Permitting claimants to continue to bring tort actions against the manufacturers and providers will not achieve desired goals, in our view, since sufficient protection is not provided from the increasingly high expense of litigation that is driving manufacturers' costs up, costs that have been asserted as forcing companies out of vaccine production and, as you have pointed out today in this hearing, costs that are being passed on to those who receive the immunization.

Beneficial legislation should strike a fair balance between the goal of compensating victims of serious vaccine injuries and the need for vaccine producing companies to operate in an environment with some measure of protection from the extremely high legal costs in this complicated, threatening area of law.

Such an environment is necessary to permit research into safer vaccines, and we must not forget the need to have vaccine developed for new illnesses, illnesses such as AIDS, herpes, or perhaps other illnesses that are, as of yet, undiscovered.

S. 827 seeks to meet the desirable goal of affording relief to individuals suffering injuries and who, otherwise, would have no remedy for compensation. By preserving the private tort remedy as an option, however, S. 827 does not overcome the factors causing most of the current problems with threatening vaccine availability.

We have reviewed pending vaccine legislation before this committee, and have again reviewed our own draft legislation on this issue, based on the recommendations of the AMA Vaccine Compensation Commission.

In view of the basic differences of approach in AMA's draft bill and pending bills, the AMA believes that we can be of most assistance to Congress by identifying amendments to bills already introduced as best achieving on a short-term basis the goals sought to be achieved.

The AMA finds both bills deficient in their present form. H.R. 1780 would pose many problems, including joint and several liability against manufacturers and others, including physicians, with physicians and public health nurses subject to personal liability, even where no fault is alleged and, in fact, where they were without fault.

The AMA remains opposed to an independent dual remedy approach, such as that found in S. 827. We therefore have recommended a series of principles for adoption in legislation and, in some cases, we suggest amendments concerning H.R. 1780. These principles are outlined in our detailed statement.

Madame Chairman, the AMA remains committed to achieving a solution to the on-going crisis in vaccine liability. Our Nation must not suffer the ravages of epidemics of preventable childhood illnesses. We must make immunization as safe as possible.

We believe that our draft bill continues to represent the best solution to problems of assuring a stable supply of vaccines, provides for prompt, fair and equitable compensation to injured patients, and also provides for the development of safer new vaccines.

Thank you very much.

[The prepared statement of Dr. Nelson and responses to questions submitted to him follow:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Committee on Labor and Human Resources
United States Senate

Presented by

Alan R. Nelson, M.D.

RE: Childhood Immunization: Problems and Options

July 18, 1985

Mr. Chairman and Members of the Committee:

My name is Alan R. Nelson, M.D. I am a physician in the practice of internal medicine in Salt Lake City, Utah. I am Vice Chairman of the AMA's Board of Trustees. With me today is Harry N. Peterson, the Director of the AMA's Division of Legislative Activities.

GENERAL COMMENTS

The American Medical Association is pleased to be before this Committee again to discuss the issues surrounding childhood immunization in this country. In our view, the most critical issue at this time is the need to assure a steady, adequate supply of needed childhood vaccines in a market characterized by unstable tort liability - an instability which has already caused disruption in vaccine supply. We are also concerned about the need to provide for fair and equitable compensation for those injured as a result of mandated pediatric immunizations.

In recent times there has been a supply disruption that has resulted in short-term shortages, rationing and postponement of important vaccine inoculations. The results of the inherent structural instability of the vaccine market could lead to more serious long-term shortages that would impact on our ability to maintain this nation's excellent immunization effort.

Last December the Centers for Disease Control recommended that due to a shortage of diptheria-tetanus-pertussis vaccine (DTP), administration of the fourth dose of DTP, usually given at 18 months of age, and the fifth dose, usually given at 4-6 years of age, be delayed until supplies are again adequate. The CDC testified before the Health Subcommittee of the House Energy and Commerce Committee last December that "unless immediate steps are taken to reduce national use of DTP, there will certainly be shortages of DTP in many areas of the country in January and February of 1985 which may continue through much of the year."

The immediate cause of this shortage was a combination of three factors: the inability of one of the manufacturers, Connaught, to obtain insurance, and therefore its cessation of marketing of its DTP vaccine; the withdrawal of another manufacturer, Wyeth, from distribution of DTP due to product liability concerns; and production difficulties with two lots of vaccine being processed by Lederle in November.

The CDC has subsequently withdrawn its rationing recommendation and DTP is once more in adequate supply due to Connaught's reentry into the market after obtaining liability protection. In addition, concerns about possibly unsuccessful efforts by Lederle to seek satisfactory insurance protection were allayed when that company announced that it obtained liability protection.

Although the short-term problem has apparently ended, the fundamental structural problems of marketing vaccines within the vaccine-injury liability climate remain. The next crisis may not be resolved as quickly and could have severe impacts on childhood immunization levels. This is especially true when considering the number of vaccines that are available only from one source.

Mr. Chairman, we all sometimes share a tendency to pay more attention to an issue during a time of crisis. However, such times are not necessarily the best times to produce good legislative solutions. With the latest emergency behind us, now is a good time to consider carefully legislation to avert the next, possibly more serious, vaccine crisis. We urge this Committee to continue to maintain vaccine-injury compensation legislation as a major priority for this session of Congress.

AMA ACTIVITIES

Mr. Chairman, when I appeared before this Committee in May of last year, the AMA's Commission on Vaccine Injury Compensation had just completed its report. This Commission, with representatives of non-medical organizations, pharmaceutical manufacturers, and government, issued a long list of recommendations. The principal recommendation of the Commission was that a federal legislative program should be pursued for the appropriate compensation of persons seriously injured as a result of mandated pediatric immunizations and such a system must be the exclusive remedy of claimants and not merely an alternative to remedies currently available. We have submitted a copy of the Commission's Report to the Committee.

The American Medical Association wholeheartedly supports this recommendation of the Commission. We have developed draft federal legislation to implement the Commission's recommendations and urge this committee to adopt this draft. A copy of our draft bill has been submitted to the Committee.

VACCINE-INJURY COMPENSATION LEGISLATION IN THE 99th CONGRESS

Two bills have been introduced in this Congress dealing with vaccine-injury compensation, H.R. 1780 and S. 827.

S. 827 - The National Childhood Vaccine Injury Compensation Act.

S. 827 is a modified version of a bill in the last Congress (S. 2117) which was the subject of this Committee's hearing on this issue in May of last year. S. 827 would establish a federal vaccine-injury compensation program. It would be a no-fault, optional avenue to compensation for persons who suffer certain injuries from designated vaccines as described in a "vaccine-injury table" set forth in the bill. Persons would have the right to make an initial decision whether to apply for government compensation or sue for damages through the traditional tort system. Payments to claimants under the compensation system would come from a trust fund constituted from surcharges levied on manufacturers of childhood vaccines . Recovery under the compensation system would be allowed for all economic losses with loss for pain and suffering limited to $100,000.

Principal differences between S. 827 and its predecessor in the 98th Congress, S. 2117, include: narrowing the list of compensable injuries to only the more severe reactions, protecting any manufacturer from liability solely due to its failure to provide direct warning to the injured party of potential dangers, and establishing a mechanism for HHS-coordinated insurance pools and reinsurance. The government program--funded by a surcharge on the vaccine--continues to be an option to the existing tort system, not the exclusive remedy.

Mr. Chairman, at this time I would like to make certain specific comments concerning S. 827, the bill before this Committee. The American Medical Association commends the sponsor of S. 827, Senator Hawkins, as well as yourself Mr. Chairman, for your continued high level of interest and effort on this important issue. It is clear that a great deal of work has gone into the drafting of this complex legislation and it is equally clear that many of the comments of interested parties on last year's version of this bill, including suggestions from the AMA, have been taken into consideration in making revisions. We appreciate the efforts of the bill sponsors in this regard.

In spite of the number of improvements in the revised version of this legislation, the AMA cannot support S. 827 because of certain fundamental provisions contained in the bill with which we strongly disagree.

Compensation Program Merely an Option. A major feature of S. 827 is the establishment of the federal compensation program as an alternative to the traditional tort remedy, rather than being the sole source of compensation for vaccine-related injuries. Given the important goals of promoting the vaccination of children and assuring the ready availability of vaccine to meet that objective, legislation should be fashioned to help achieve those goals. Permitting claimants to continue to bring tort actions against manufacturers and providers will not achieve desired goals, in our view, since sufficient protection is not provided from the increasingly high expense of litigation that is driving manufacturer costs up--costs that have been asserted as forcing companies out of vaccine production.

Beneficial legislation should strike a fair balance between the desirable goal of compensating victims of serious vaccine injuries and the need for vaccine producing companies to operate in an environment with some measure of protection from the extremely high legal costs in this complicated and threatening area of law. S. 827 seeks to meet the desirable goal of affording relief to individuals suffering injuries and who otherwise would have no remedy for compensation. By preserving the private tort remedy as an option, however, S. 827 does not overcome the factors causing current problems and thus would not promote the desirable goal of providing for continued availability of vaccines at reasonable costs and maximum immunization coverage of our population.

Statutory Vaccine Injury Table. S. 827 contains a Vaccine-Injury Table that lists the compensable events and time periods for onset of those events; the Table is an integral part of the legislation and would be used to determine eligibility for compensation.

We note with satisfaction that the Vaccine-Injury Table no longer contains the long list of minor reactions and that the Table now focuses on those few reactions recognized as severe. However, the AMA continues to strongly recommend against having any compensable injuries listed in legislation. The nature of vaccine injuries militates against listing in a statute the specific events and time periods for onset. Identification of compensable events through administrative regulations is a more desirable alternative. Regulations are more flexible and amenable to changes reflecting new developments in the immunization field and permit the on-going input and advice of scientific experts. The legislative format precludes necessary flexibility and application of individualized medical judgment. The rigidity of the legislative approach should be avoided.

Funding through Surcharges on Vaccine Manufacturers. The bill does not address the increasing costs of vaccines. We are concerned that the surcharge method of financing will only accelerate the already high costs of vaccine since it adds to current costs by virtue of adoption of the new system of compensation. Because the entire population benefits from immunization, not just those immunized, a more appropriate financing system might be one that ultimately relies on general revenue funding.

Medical Practice Standards. S. 827 would require the HHS Secretary to issue regulations defining the circumstances under which covered vaccines should not be administered, the circumstances under which administration of a vaccine should be delayed beyond its usual time, and the groups, categories, or characteristics of potential recipients of such vaccine who may be at higher risk of major adverse reaction than the general population.

The required HHS regulations would strongly impact on medical practice and questions of professional judgment and liability. We object to such standards being laid down by the Secretary of HHS.

Other Concerns. In addition to these major concerns, questions are also raised relating to the immunizations covered, statute of limitations, and the definition of "maximum feasible potential" in the context of medical expense reimbursement.

H.R. 1780 - The National Childhood Vaccine-Injury Compensation Act.

H.R. 1780 would establish a modified no-fault system for vaccine-compensation that requires all claims for damages allegedly caused by a vaccine to be first submitted to a three-person hearing panel. All potential claimants must file their claim in the "no-fault" compensation program, naming parties involved. Respondents elect whether to participate, but failure to participate exposes them to civil tort action and to unlimited damages in such an action. The panel would determine causation and if the panel determined that the injury was "vaccine-related" it could make an award for actual damages of up to $1 million including pain and suffering. An award for pain and suffering could not exceed $100,000. Liability actions could still be filed in cases where the injured party does not accept the award offered (though maximum damages would be limited by the caps in cases where a respondent did participate in the compensation process).

AMA BILL

Mr. Chairman, the American Medical Association has carefully reviewed H.R. 1780, S. 827, and again reviewed our own draft bill. While all the bills have common objectives, the principal ones being the continuing availability of vaccines, the furnishing of equitable compensation of persons injured by adverse reactions, and the appropriate vaccination of all children, it is our belief that the AMA bill presents the soundest approach to best achieve the goals. We recognize, however, that circumstances have changed with the introduction H.R. 1780 inasmuch as the bill is supported by certain vaccine manufacturers, who apparently prefer a modified no-fault approach such as that in H.R. 1780 to the exclusive remedy provided in the AMA draft bill.

SUGGESTED CHANGES TO PENDING BILLS

In view of the basic differences of approach in AMA's bill and pending bills, the AMA believes that we can be of most assistance to the Congress by identifying amendments to bills already introduced as best achieving on a short-term basis the goals sought to be achieved.

The American Medical Association finds both bills unacceptable in their present form. H.R. 1780 would pose many problems including joint and several liability against manufacturers and others (including physicians), with physicians being subject to personal liability even where no fault is alleged and in fact the physician was without fault. While the bill intends a subsequent civil tort action to determine equities among all the parties (defendants) in order to establish comparative negligence and equitable allocation of penalty based on fault, under the bill liability would finally rest upon the manufacturers where negligence was not established against any other persons.

The AMA remains opposed to an independent dual remedy approach such as is found in S. 827. We recommend the following principles for adoption in legislation, and in some cases we suggest amendments concerning H.R. 1780:

1. Modified No-Fault System. An effective way to assure a continued supply of vaccines, their timely administration and promotion of public participation, is to remove vaccine injury cases from the existing tort system. A proposed compensation system can embrace a modified no fault compensation program by using a system similar to that proposed in H.R. 1780.

   The legislation should provide a no-fault entry into the claims review process. Claims for damages in the compensation program contemplated in H.R. 1780, however, should be assessed only against manufacturers. Manufacturers should be allowed to recover all expenses and compensation payments from any party who was at fault. If more then one party was at fault, damages would be apportioned to reflect comparative negligence.

2. Scope of Coverage. All persons seriously injured as a result of state mandated pediatric immunizations should be compensated.

3. Compensable Events. The legislation should direct the Secretary of Health and Human Services to appoint an expert advisory group to define through administrative procedures those injuries and adversities that would be compensable under the program. Until such time as the final list is developed, a table of serious compensable events as found in S. 827 could be used. The advisory panel would have the authority to add to or delete from or otherwise modify the table.

4. Extent of Compensation. Awards should cover:

   - medical and other needed care, rehabilitation and other compensatory payments not reimbursed by other programs;
   - compensation to reflect future earnings;
   - limited payments for pain and suffering;
   - prohibition of punitive and exemplary damages;
   - requirement for structured settlements for payments of future damages exceeding $100,000;
   - reasonable limits on fees to legal counsel arising out of awards paid to claimants, recognizing the time, effort, expense and complexity of the case, but in no case shall such fees exceed 10% of the award;
   - a provision for a death benefit.

5. Amount of Compensation. Specific dollar amounts to be awarded should be based on a formula developed administratively by an advisory committee to HHS comprised of experts with experience in this type of economic analysis.

6. Judicial Review. The legislation should provide that the compensation panel's determination on compensation eligibility and the amount of damages shall enjoy a presumption that substantial evidence supports the final judgment.

7. Vaccines Covered. Vaccines mandated by states and the federal government should be covered such as those listed in S. 827:

   DTP, P, DTP/Polio combination, or any other vaccine containing whole cell pertussis bacteria, extracted or partial cell bacteria, or specific pertussis antigens; MMR, Measles, DT, Td, Tetanus Toxoid, Mumps, Rubella vaccine; Polio vaccines; and Inactivated Polio vaccines.

8. Safer Vaccines - Research. A commission within the NIH should be created to encourage and fund research for the development of safer vaccines.

9. Patient Information. Provide for information similar to that required by H.R. 1780 to be given to parents.

CONCLUSION

Mr. Chairman, the AMA remains committed to achieving a solution to the on-going crisis in vaccine liability. We believe that our draft bill continues to represent the best solution to the problems of assuring a stable supply of childhood vaccines and provide prompt, fair and equitable compensation to injured patients. However, we also urge this Committee to consider those amendments that we have identified to H.R. 1780. As amended, we believe that such legislation, with limitations for recovery and founded on a compensation system, can significantly improve the vaccine supply situation for many years to come.

2002p

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JAMES H. SAMMONS, M.D.
Executive Vice President
(645-4300)

August 14, 1985

The Honorable Orrin G. Hatch
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510

Dear Chairman Hatch:

The written questions submitted to Alan Nelson, M.D., by the Labor and Human Resources Committee--the answers to which are to be included in the record of the hearing of July 18, 1985--were referred to the AMA staff for response.

The answers to the five questions from the Committee, as well as the additional sixth question from Senator Grassley, are enclosed.

Sincerely,

James H. Sammons, M.D.

JHS:ss
Enclosure

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ANSWERS TO WRITTEN QUESTIONS
SUBMITTED TO ALAN NELSON, M.D.,
FROM THE SENATE LABOR AND HUMAN RESOURCES COMMITTEE

August 14, 1985

1. Q The AMA Vaccine Task Force recommended a legislative approach that would have offered an administrative compensation system as an "exclusive remedy" for injured parties. There are many who believe that eliminating citizens' rights to pursue claims in torts is unjust. Will you comment on this?

A The American tort system for allocating responsibility and assessing damages due to negligence has generally produced just results. There are a few particular areas, however, where the tort system does not best serve the public interest. Workmens compensation programs to deal with injuries in the workplace is one example where the public interest is well served through limitations on tort action.

We believe that vaccine-injury cases are another example where the public will benefit from limits on litigation claims. We believe that it is unjust for a child to be required, for the good of society, to receive a pediatric vaccination and then perhaps go without any compensation if he or she is injured by that vaccine with no negligence on anyone's part. The AMA proposal balances the equities by providing prompt compensation for economic loss regardless of fault to assure fair compensation to all severely injured parties. The improved justice achieved in this way, combined with the social value of maintaining adequate supplies of life-saving vaccines, far outweighs any social value achieved by a handful of families having the right to seek potentially windfall monetary judgments.

2. Q What is the AMA doing to assure that doctors and patients are better informed about contraindications and side effects of vaccines?

A The AMA has conducted a number of activities to help assure that physicians and patients are informed about contraindications and side effects of vaccines. The AMA publishes AMA Drug Evaluations which details these contraindications and side effects. In the upcoming Sixth Edition of AMA DE, the chapter "Agents for Active & Passive Immunization" is twice the length it was in the Fifth Edition. Currently, it is the longest chapter in the book.

The AMA includes a section entitled "Leads from the MMWR" (Morbidity and Mortality Weekly Report of the Centers for Disease Control) in every week's issue of the Journal of the American Medical Association. The MMWR leads are also conveyed through AMA-NET, the AMA's computerized medical information network. The

MMWR reports often contains discussions of vaccine reaction incidence, as indicated in the recently published example attached.

The AMA has published a brochure entitled "Immunization" designed for reading by patients which, on its first page, discusses adverse reactions to vaccines.

Moreover, the Association would support, as part of a legislative solution to immunization program problems, a parent information provision similar to that which is found in H.R. 1780.

3. Q Do you believe that more research is needed to produce a safer pertussis vaccine, or do we now have available the best possible product?

A Yes, more research is needed. The AMA supports establishing a Commission within the National Institutes of Health to encourage and fund research for the development of safe and efficacious vaccines.

4. Q What can be done to improve the accuracy of our records on the numbers of adverse reactions and side effects of vaccines? Would it be possible to establish a system of mandatory reporting by all physicians? How would such a system be enforced, and would physicians willingly participate?

A Currently, adverse reactions to vaccines that are administered through state public health departments must be reported to the Centers for Disease Control. This reporting is very good with respect to severe vaccine reactions. Since 50% of all mandatory pediatric vaccines are administered by public health departments, proposals to, in effect, double this sample size by requiring private physicians to engage in similar reporting would not achieve any gain in our understanding of the incidence of such severe reactions.

Minor reactions are not fully reported by public health departments at present. Accordingly, we would support a pilot project to extend public health reporting to all adverse reactions from mandated vaccines.

5. Q Do you believe that a "no-fault" compensation system, such as that proposed in S. 827, essentially gets negligent physicians "off the hook?"

A No. The system proposed by S. 827 provides for the Trust Fund to be subrogated to the rights of the petitioner with respect to the vaccine injury. Pursuant to such subrogation, the bill permits the Secretary of HHS to bring civil action to recover appropriate damages. The civil action could be filed against any negligent party or parties, including the physician or health care provider who administered the vaccine. The AMA draft bill includes a similar provision and we would support a clear direction to the HHS Secretary to follow up on all cases where negligence is a factor in the injury.

6. Q (From Senator Grassley) From your perspective as practicing physicians and as individuals with an obvious interest in this issue and obvious considerable knowledge about what is going on in your profession, would you agree with the parents' groups argument to the effect that there is great underestimation of the incidence of adverse reactions to vaccines?

A With regard to major reactions we do not believe underreporting to be the case. As indicated in our response to Question #4, 50% of mandatory pediatric vaccines are administered by state public health departments who are required to report major adverse reactions. Their reporting of serious reactions is very good and, since they constitute 50% of vaccine administrations, it is unlikely that the incidence of severe reactions in this country is being underestimated. It is possible that the incidence of minor reactions (sore arms, fevers) is underreported. Therefore, it may be desirable to establish a pilot program for better collection of minor adverse reaction data from state public health departments.

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Leads from the MMWR

Morbidity and Mortality Weekly Report (Vol 34/No 27, 1985), Centers for Disease Control, Atlanta

Diphtheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures

This revision of the Immunization Practices Advisory Committee (ACIP) statement on diphtheria, tetanus, and pertussis updates the statement issued in 1981[1] and incorporates the 1984 supplementary statement on the risks of pertussis disease and pertussis vaccine for infants and children with personal histories of convulsions.[2] It includes a review of the epidemiology of the three diseases, a description of the available immunobiologic preparations, and the appropriate immunization schedules. Also included are revisions in the schedule for combined diphtheria and tetanus toxoids (DT), when pertussis vaccine is contraindicated, and revisions in the recommendations on precautions and contraindications to vaccine use, on immunization for infants and children who have underlying neurologic disorders, and on tetanus prophylaxis in wound management.

Introduction

Simultaneous immunization against diphtheria, tetanus, and pertussis during infancy and childhood has been a routine practice in the United States since the late 1940s. This practice has played a major role in markedly reducing the incidence rates of cases and deaths from each of these diseases.

Diphtheria

At one time, diphtheria was common in the United States. More than 200,000 cases, primarily among children, were reported in 1921. Approximately 5% to 10% of cases were fatal; the highest case-fatality ratios were among the very young and the elderly. Reported cases of diphtheria of all types declined from 306 in 1975 to 59 in 1979; most were cutaneous diphtheria reported from a single state. After 1979, cutaneous diphtheria was no longer reportable. From 1980 through 1983, only 15 cases of respiratory diphtheria were reported; 11 occurred among persons 20 years of age or older.

The current rarity of diphtheria in the United States is due primarily to the high level of appropriate immunization among children (96% of children entering school have received three or more doses of diphtheria and tetanus toxoids and pertussis vaccine [DTP]) and to an apparent reduction of the circulation of toxigenic strains of *Corynebacterium diphtheriae*. Most cases occur among unimmunized or inadequately immunized persons. The age distribution of recent cases and the results of serosurveys indicate that many adults in the United States are not protected against diphtheria. Thus, it appears that more emphasis should be placed on adult immunization programs.

Both toxigenic and nontoxigenic strains of *C diphtheriae* can cause disease, but only strains that produce toxin cause myocarditis and neuritis. Furthermore, toxigenic strains are more often associated with severe or fatal illness in noncutaneous (respiratory or other mucosal surface) infections and are more commonly recovered from respiratory than from cutaneous infections.

Corynebacterium diphtheriae can contaminate the skin of certain persons, usually at the site of a wound. Although a sharply demarcated lesion with a pseudomembranous base often results, the appearance may not be distinctive, and the infection can be confirmed only by culture. Usually, other bacterial species can also be isolated. Cutaneous diphtheria has most commonly affected indigent adults and certain groups of Native Americans.

Complete immunization significantly reduces the risk of developing diphtheria, and immunized persons who develop disease have milder illnesses. Protection is thought to last at least ten years. Immunization does not, however, eliminate carriage of *C diphtheriae* in the pharynx or nose or on the skin.

Tetanus

The occurrence of tetanus in the United States has decreased markedly because of the routine use of tetanus toxoid. Nevertheless, the number of reported cases has remained relatively constant in the last decade at an annual average of 90 cases. In 1983, 91 tetanus cases were reported from 29 states. In recent years, approximately two thirds of patients have been 50 years of age or older. The age distribution of recent cases and the results of serosurveys indicate that many US adults are not protected against tetanus. The disease has occurred almost exclusively among persons who are unimmunized or inadequately immu-

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This is the first part of the ACIP's updated guidelines on prevention of diphtheria, tetanus, and pertussis. The conclusion of the statement will be published in next week's LEADS FROM THE MMWR.

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nized or whose immunization histories are unknown or uncertain.

In 6% of tetanus cases reported during 1982 and 1983, no wound or other condition could be implicated. Nonacute skin lesions, such as ulcers, or medical conditions, such as abscesses, were reported in 17% of cases.

Neonatal tetanus occurs among infants born under unhygienic conditions to inadequately immunized mothers. Immune pregnant women confer protection to their infants through transplacental maternal antibody. From 1974 through 1983, 20 cases of neonatal tetanus were reported in the United States.

Spores of *Clostridium tetani* are ubiquitous. Serologic tests indicate that naturally acquired immunity to tetanus toxin does not occur in the United States. Thus, universal primary immunization, with subsequent maintenance of adequate antitoxin levels by means of appropriately timed boosters, is necessary to protect persons in all age groups. Tetanus toxoid is a highly effective antigen, and a completed primary series generally induces protective levels of serum antitoxin that persist for ten or more years.

Pertussis

General use of standardized pertussis vaccine has resulted in a substantial reduction in cases and deaths from pertussis disease. However, the annual number of reported cases has changed relatively little during the last ten years, when annual averages of 1,835 cases and ten fatalities have occurred. In 1983, 2,463 cases were reported; in 1981, the latest year for which final national mortality statistics are available from the National Center for Health Statistics, six deaths were recorded. More precise data do not exist, since many cases go unrecognized or unreported, and diagnostic tests for *Bordetella pertussis*—culture and direct-immunofluorescence assay (DFA)—may be unavailable, difficult to perform, or incorrectly interpreted.

For 1982 and 1983, 53% of reported illnesses from *B pertussis* occurred among children younger than 1 year of age, and 78%, among children younger than 5 years of age. 13 of 15 deaths reported to the CDC occurred among children younger than 1 year old. Before widespread use of DTP, about 20% of cases and 50% of pertussis-related deaths occurred among children younger than 1 year old.

Pertussis is highly communicable (attack rates of more than 90% have been reported in unimmunized household contacts) and can cause severe disease, particularly in very young children. Of patients younger than 1 year of age reported to the CDC during 1982 and 1983, 75% were hospitalized; approximately 22% had pneumonia; 2% had one or more seizures; and 0.7% died. Because of the substantial risks of complications of the disease, completion of a primary series of DTP early in life is essential.

In older children and adults—including, in some instances, those previously immunized—infection may result in nonspecific symptoms of bronchitis or an upper respiratory tract infection, and pertussis may not be diagnosed because classic signs, especially the inspiratory whoop, may be absent. Older preschool-aged children and school-aged siblings who are not fully immunized and develop pertussis can be important sources of infection for young infants—the group at highest risk of disease and disease severity. The importance of the infected adult in overall transmission remains to be defined.

Controversy regarding use of pertussis vaccine led to a formal reevaluation of the benefits and risks of this vaccine. The analysis indicated that the benefits of the vaccine continue to outweigh its risks.[8]

Because the incidence rate and severity of pertussis decrease with age, and because the vaccine may cause side effects and adverse reactions, pertussis immunization is not recommended for children after the seventh birthday, except under unusual circumstances (see "Vaccine Usage").

Preparations Used for Immunization

Diphtheria and tetanus toxoids are prepared by formaldehyde treatment of the respective toxins and are standardized for potency according to the regulations of the US Food and Drug Administration (FDA). The Lf content of each toxoid (quantity of toxoid as assessed by flocculation) may vary among different products. Because adverse reactions to diphtheria toxoid are apparently directly related to the quantity of antigen and to the age of the recipient, the concentration of diphtheria toxoid in preparations intended for use in adults is reduced.

Pertussis vaccine is a suspension of inactivated *B pertussis* cells. Potency is assayed by comparison with the US Standard Pertussis Vaccine in the intracerebral mouse protection test. The protective efficacy of pertussis vaccines in humans has been shown to correlate with the potency of vaccines.

Diphtheria and tetanus toxoids and pertussis vaccine, as single antigens or various combinations, are available as aluminum salt adsorbed preparations. Only tetanus toxoid is available in nonadsorbed (fluid) form. Although the rate of seroconversion is essentially equivalent with either type of tetanus toxoid, the adsorbed toxoid induces a more persistent antitoxin titer.

The two toxoids and the pertussis vaccine are currently available in the United States as the following preparations:

1. Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP) and Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use) (DT)* are combinations for use in infants and children younger than 7 years old.
2. Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use) (Td) is a combined preparation for use in persons 7 years old and older.
3. Pertussis Vaccine Adsorbed (P)†, Tetanus Toxoid (Fluid), Tetanus Toxoid Adsorbed (T), and Diphtheria Toxoid Adsorbed (D)‡, are single-antigen products for use in instances when combined antigen preparations are not indicated.

Work is in progress to develop an effective acellular pertussis vaccine with a reduced reaction rate. Current research is directed toward development of a vaccine consisting principally of one or more of the

*Table 1.—Routine diphtheria, tetanus, and pertussis immunization schedule summary for children younger than 7 years old—United States, 1985**

Dose	Age/Interval†	Product
Primary 1	6 wk old or older	DTP†¶
Primary 2	4-8 wk after first dose§	DTP¶
Primary 3	4-8 wk after second dose§	DTP¶
Primary 4	6-12 mo after third dose§	DTP¶
Booster	4-6 yr old, before entering kindergarten or elementary school (not necessary if fourth primary immunizing dose administered on or after fourth birthday)	DTP¶
Additional boosters	Every 10 yr after last dose	Td

*Important details are in the text.

†Customarily begun at 6 weeks of age, with second and third doses given at eight-week intervals.

§Prolonging the interval does not require restarting series.

¶DT, if pertussis vaccine is contraindicated. If the child is 1 year of age or older at the time the primary dose is given, a third dose six to 12 months after the second completes primary immunization with DT.

bacterial components thought to provide protection. Prominent candidate antigens include filamentous hemagglutinin and lymphocytosis promoting factor (pertussis toxin). However, several years will be necessary to complete development and to document the potency, safety, and efficacy of a new vaccine.

Vaccine Usage

The standard single-dose volume of DTP, DT, Td, single-antigen adsorbed preparations of pertussis vaccine, tetanus toxoid, and diphtheria toxoid, and the nonadsorbed tetanus toxoid is 0.5 mL. Adsorbed preparations should be administered intramuscularly (IM). Vaccine administration by jet injection may be associated with more frequent local reactions. (See also ACIP. General recommendations on immunization. *MMWR* 1983;32:1-8, 13-17.)

Primary Immunization

Children 6 weeks through 6 years old (up to the seventh birthday) (Table 1).—One dose of DTP should be given IM on four occasions—the first three doses at four- to eight-week intervals, beginning when the infant is approximately 6 weeks to 2 months old. The fourth dose is given approximately six to 12 months after the third to maintain adequate immunity for the ensuing preschool years. This dose is an integral part of the primary immunizing course. If a contraindication to pertussis vaccination exists (see "Precautions and Contraindications"), DT should be substituted for DTP as outlined under "Special Considerations."

Persons 7 years old and older and adults (Table 2).—Pertussis-containing preparations are not recommended routinely in these age groups. A series of three doses of Td should be given IM; the second dose is given four to eight weeks after the first; and the third dose, six to 12 months after the second. Td rather than DT is the agent of choice for immunization of all patients 7 years old and older, because side effects from higher doses of diphtheria toxoid are more common in older children and adults.

Interruption of primary immunization schedule.—Interrupting the recommended schedule or delaying subsequent doses probably does not lead to a reduction in the level of immunity reached on completion of the primary series. Therefore, there is no need to restart a series regardless of the time elapsed between doses.

Booster Immunization

Children 4 to 6 years old (up to the seventh birthday).—Those who received all four primary immunizing doses before the fourth birthday should receive a single dose of DTP just before entering kindergarten or elementary school. This booster dose is not necessary if the fourth dose in the primary series was given on or after the fourth birthday.

Persons 7 years old and older.—Tetanus toxoid should be given with diphtheria toxoid as Td every ten years. If a dose is given sooner as part of wound management, the next booster is not needed for ten years thereafter (see "Tetanus Prophylaxis in Wound Management"). More frequent boosters are not indicated and have been reported to result in an increased occurrence and severity of adverse reactions. One means of ensuring that persons receive boosters every ten years is to vaccinate persons routinely at mid-decade ages, that is, 15 years, 25 years, 35 years, and so on.

Special Considerations

Children with a contraindication to pertussis vaccination (see "Precautions and Contraindications").—For children younger than 7 years old with a contraindication to pertussis vaccine, DT should be used rather than DTP. To ensure that there will be no interference with the antigens from maternal antibodies, unimmunized children younger than 1 year of age receiving their first DT dose should receive a total of four doses of DT as the primary series, the first three doses of four- to eight-week intervals and the fourth dose six to 12 months later (similar to the recommended DTP schedule). If further doses of pertussis vaccine become contraindicated after beginning a DTP series in the first year of life, DT should be substituted for each of the remaining scheduled DTP doses.

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*Table 2.—Routine diphtheria and tetanus immunization schedule summary for persons 7 years old and older—United States, 1985**

Dose	Age Interval	Product
Primary 1	First dose	Td
Primary 2	4-8 wk after first dose†	Td
Primary 3	6-12 mo after second dose†	Td
Boosters	Every 10 yr after last dose	Td

*Important details are in the text.
†Prolonging the interval does not require restarting series.

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Unimmunized children 1 year of age or older for whom DTP is contraindicated should receive two doses of DT four to eight weeks apart, followed by a third dose six to 12 months later to complete the primary series. Children 1 year of age or older who have received one or two doses of DT or DTP and for whom further pertussis vaccine is contraindicated should receive a total of three doses of a preparation containing diphtheria and tetanus toxoids, with the third dose given six to 12 months after the second.

Children who complete a primary series of DT before the fourth birthday should receive a single dose of DT just before entering kindergarten or elementary school. This dose is not necessary if the last dose of the primary series was given on or after the fourth birthday.

Pertussis immunization for persons 7 years old or older.—Routine immunization against pertussis is not recommended for persons 7 years old and older. In exceptional cases, such as persons with chronic pulmonary disease exposed to children with pertussis or medical personnel exposed during nosocomial or community outbreaks, a booster dose of adsorbed pertussis vaccine may be considered. A reduced dose is used for adults.[4] Routine pertussis vaccination of hospital personnel is not recommended.

Persons recovering from tetanus or diphtheria.—Tetanus or diphtheria infection may not confer immunity; therefore, active immunization should begin at the time of recovery from the illness, and arrangements made to ensure that the remaining doses of a primary series are given as early as possible.

Children recovering from pertussis.—Children who have recovered from culture-confirmed pertussis need not receive further doses of pertussis vaccine. Lacking culture confirmation of the diagnosis, DTP immunization should be completed, because a pertussislike syndrome may have been caused by other *Bordetella* species, chlamydia, or some viruses.

Neonatal tetanus prevention.—There is no evidence that tetanus and diphtheria toxoids are teratogenic. A previously unimmunized pregnant woman who may deliver her child under unhygienic circumstances or surroundings should receive two properly spaced doses of Td before delivery, preferably during the last two trimesters. Incompletely immunized pregnant women should complete the three-dose series. Those immunized more than ten years previously should have a booster dose.

Adult immunization with Td.—Limited serosurveys done since 1977 indicate that the proportion of the population lacking protective levels of circulating antitoxin against diphtheria and tetanus increases with increasing age and that at least 40% of persons 60 years of age or older lack protective levels of antitoxins. Every time an adult visits a medical provider should be an opportunity to assess the patient's immunization status and, if indicated, to provide protection against tetanus and diphtheria using the combined toxoid, Td. Adults with uncertain histories of a complete primary series should receive a primary series. To ensure continued adequate protection in the patient, booster doses of Td could be given routinely at mid-decade ages, that is, 15 years, 25 years, 35 years, and so on.

Use of Single-Antigen Preparations

Multiple-antigen preparations should be used, unless there is a contraindication to one or more antigens in a preparation.

A single-antigen adsorbed pertussis vaccine preparation may be used to complete immunization against pertussis for children younger than 7 years of age who have received fewer than the recommended number of doses of pertussis vaccine but have received the recommended number of doses of diphtheria and tetanus toxoids for their age. Alternatively, doses of DTP can be given for protection against pertussis, although it is suggested that the total number of doses of diphtheria and tetanus toxoids not exceed six each before the seventh birthday.

Available data do not indicate substantially more reactions following receipt of Td than following receipt of single-antigen, adsorbed tetanus toxoid. Furthermore, adults, in general, are even less likely to have adequate circulating levels of diphtheria antitoxin than adequate circulating levels of tetanus antitoxin. The routine use of Td in all medical settings, for example, private practice, clinics, and emergency rooms, for all persons 7 years of age or older requiring primary immunization or booster doses will improve levels of protection against both tetanus and diphtheria, especially among adults.

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*Available from several manufacturers.
†Distributed by the Biologics Products Program, Michigan Department of Public Health, for use within that state; may be available for use outside Michigan under special circumstances by consultation with that program.
‡Distributed by Sclavo, Inc.

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To be continued in the Aug 23/30 JAMA

Leads from the MMWR

Morbidity and Mortality Weekly Report (Vol. 34/No. 27, 1985), Centers for Disease Control, Atlanta

Diphtheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures

The following report concludes the ACIP's recommendations on diphtheria, tetanus, and pertussis vaccine prophylaxis and prevention. The first part of the ACIP's guidelines was published in last week's LEADS FROM THE MMWR (JAMA 1985;254:895-900).

Side Effects and Adverse Reactions

Local reactions, generally erythema and induration with or without tenderness, are common after the administration of vaccines containing diphtheria, tetanus, or pertussis antigens. Occasionally, a nodule may be palpable at the injection site of adsorbed products for several weeks. Abscesses at the site of injection have been reported (six to ten per million doses). Mild systemic reactions, such as fever, drowsiness, fretfulness, and anorexia, occur quite frequently. These reactions are significantly more common following DTP than following DT, are usually self-limited, and need no therapy other than, perhaps, symptomatic treatment (for example, antipyretics).

Moderate to severe systemic events, such as fever of 40.5 °C (105 °F) or higher, persistent, inconsolable crying lasting three hours or longer, unusual high-pitched crying, collapse, or convulsions, occur relatively infrequently. Other more severe neurologic complications, such as a prolonged convulsion or an encephalopathy, occasionally fatal, have been reported to be associated with DTP administration, although rarely.

Approximate rates for adverse events following receipt of DTP vaccine (regardless of dose number in the series) are indicated in Table 3.[5,6]

The frequency of local reactions and fever following DTP vaccination is significantly higher with increasing numbers of doses of DTP, while other mild to moderate systemic reactions (for example, fretfulness and vomiting) are significantly less frequent.[5] If local redness of 2.5 cm or larger occurs, the likelihood of recurrence after another DTP dose increases significantly.

In the National Childhood Encephalopathy Study (NCES), a large, case-control study in England,[7] children 2 to 35 months of age with serious, acute neurologic disorders, such as encephalopathy or complicated convulsion(s), were more likely to have received DTP in the seven days preceding onset than their age-, sex-, and neighborhood-matched controls. Among children known to be neurologically normal before entering the study, the relative risk§ of a neurologic illness occurring within the seven-day period following receipt of DTP dose, compared with children not receiving DTP vaccine in the seven-day period before onset of their illness, was 3.3 ($P<0.001$). Within this seven-day period, the risk was significantly increased for immunized children only within three days of vaccination (relative risk, 4.2; $P<0.001$). The relative risk for illness occurring four to seven days after vaccination was 2.1 ($0.05<P<0.1$). The attributable risk estimates for a serious acute neurologic disorder within seven days after receiving DTP vaccine (regardless of outcome) was one in 110,000 doses of DTP, and for a permanent neurologic deficit, one in 310,000 doses. No specific clinical syndrome was identified. Overall, DTP vaccine accounted for only a small proportion of cases of serious neurologic disorders reported in the population studied.

Although there are uncertainties in the reported studies, recent data suggest that infants and young children who have had previous convulsions (whether febrile or afebrile) are more likely to have seizures following DTP vaccination than those without such histories.[8]

Rarely, an anaphylactic reaction (that is, hives, swelling of the mouth, difficulty breathing, hypotension, or shock) has been reported after receiving preparations containing diphtheria, tetanus, and/or pertussis antigens. The ACIP finds no good evidence for a causal relationship between DTP and hemolytic anemia or thrombocytopenic purpura.

Arthus-type hypersensitivity reactions, characterized by severe local reactions (generally starting two to eight hours after an injection), may follow receipt of tetanus toxoid, particularly in adults who have

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received frequent or annual boosters of tetanus toxoid. A few cases of peripheral neuropathy have been reported following tetanus toxoid administration, although a causal relationship has not been established.

Sudden infant death syndrome (SIDS) has occurred in infants following administration of DTP. A large case-control study of SIDS in the United States showed that receipt of DTP was not causally related to SIDS.[9] It should be recognized that the first three primary immunizing doses of DTP are usually administered to infants two to six months old and that approximately 85% of SIDS cases occur at ages 1 to 6 months, with the peak incidence occurring between 6 weeks and 4 months of age. By chance alone, some SIDS victims can be expected to have recently received vaccine.

Onset of infantile spasms has occurred in infants who have recently received DTP or DT. Analysis of data from the NCES on children with infantile spasms showed that receipt of DTP or DT was not causally related to infantile spasms.[10] The incidence of onset of infantile spasms increases at 3 to 9 months of age, the time period in which the second and third doses of DTP are generally given. Therefore, some cases of infantile spasms can be expected to be related by chance alone to recent receipt of DTP.

Reporting of Adverse Events

Reporting by parents and patients of all adverse events occurring within four weeks of antigen administration should be encouraged. Adverse events that require a visit to a medical provider should be reported by the providers to vaccine manufacturers and local or state health departments. The information will be forwarded to an appropriate federal agency (the Bureau of Biologics Research and Review, FDA, or CDC).

Table 3 — Adverse events occurring within 48 hours of DTP immunizations

Event	Frequency*
Local	
Redness	1/3 doses
Swelling	2/5 doses
Pain	1/2 doses
Mild/moderate systemic	
Fever ≥38 °C (100.4 °F)	1/2 doses
Drowsiness	1/3 doses
Fretfulness	1/2 doses
Vomiting	1/15 doses
Anorexia	1/5 doses
More serious systemic	
Persistent, inconsolable crying (duration ≥3 hr)	1/100 doses
High-pitched, unusual cry	1/900 doses
Fever ≥40.5 °C (≥105 °F)	1/330 doses
Collapse (hypotonic-hyporesponsive episode)	1/1,750 doses
Convulsions (with or without fever)	1/1,750 doses
Acute encephalopathy†	1/110,000 doses
Permanent neurologic deficit†	1/310,000 doses

*Number of adverse events per total number of doses regardless of dose number in DTP series.

†Occurring within seven days of DTP immunization.

Comments on Using Reduced-Dosage Schedules or Multiple Small Doses

The ACIP recommends giving only the full dose of DTP; if a specific contraindication to DTP exists, none should be given. In the United States, the full course of primary immunization is considered to be four 0.5-mL doses of DTP.

Concern about adverse events following pertussis vaccination has led some practitioners to reduce the volume of DTP administered to less than 0.5 mL per dose in an attempt to reduce side effects. There is no evidence that a reduction in dosage decreases the frequency of severe events, such as seizures, hypotonic-hyporesponsive episodes, and encephalopathy. The mechanisms for these reactions are not known. Some studies reported significantly lower rates of local reactions to half the recommended dose (0.25 mL), compared with those following a full dose.[7,11] A recent study also showed significantly lower pertussis serologic responses after the second and third half-doses, although the differences were small.[11] This investigation used pertussis agglutinins as a measure of clinical protection; however, agglutinins are not absolute measures of clinical protection against pertussis disease. Furthermore, there is no evidence that the low screening titer used in this investigation (1:16) is indicative of protection. Currently, there are no reliable measures of efficacy other than clinical protection. Further evidence against the use of reduced doses comes from earlier studies of vaccine[12,13] with potency equivalent to that of half-doses of current vaccine. Attack rates of pertussis for exposed household contacts who received a lower potency vaccine (equivalent to a half-dose of the current vaccine) were approximately twice as high as attack rates for exposed household contacts who had received vaccines of potency equivalent to full doses of current vaccine (29%, compared with 14% or lower).

The use of an increased number of reduced-volume doses of DTP to equal the total volume of the five recommended doses of DTP vaccine is not recommended. It is unknown whether such a practice reduces the likelihood of vaccine-related events. In addition, by increasing the number of immunizations, the likelihood of a temporally associated but etiologically unrelated event may be enhanced.

Neither the use of reduced individual DTP doses nor the use of multiple doses of reduced volume that, in total, equal a full immunizing dose has been adequately studied. Neither the efficacy of such practices in reducing the frequency of associated serious adverse events nor the resulting protection against disease have been determined.

Simultaneous Administration of Vaccines

The simultaneous administration of DTP, oral polio virus vaccine (OPV), and/or measles-mumps-rubella vaccine (MMR) has resulted in seroconversion rates and rates of side effects similar to those observed when the vaccines are administered separately.[14] Therefore, if there is any doubt that a vaccine recipient will return for further vaccine doses, the ACIP recommends the simultaneous administration of all vaccines appropriate to the age and previous vaccination status of the recipient. This would especially include the simultaneous administration of DTP, OPV, and MMR to such persons at 15 months of age or older.

Precautions and Contraindications

A febrile illness is reason to defer routine vaccination. Minor illness, such as mild upper respiratory infection, should not ordinarily be a reason for postponing vaccination. A history of prematurity generally is not a reason to defer vaccination.[15]

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater-than-physiologic doses), may reduce the immune response to vaccines. Short-term (less than two weeks) corticosteroid therapy or intra-articular, bursal, or tendon injections with corticosteroids should not be immunosuppressive. Although no specific studies with pertussis vaccine are available, if immunosuppressive therapy will be discontinued shortly, it would be reasonable to defer immunization until the patient has been off therapy for one month,[illegible] otherwise, the patient should be vaccinated while still on therapy.

When an infant or child returns for the next dose of DTP, the parent should be questioned about any adverse events occurring after the previous dose.

Pertussis-Containing Preparations

Absolute Contraindications.—If any of the following adverse events occur after DTP or single-antigen pertussis vaccination, further vaccination with a vaccine containing pertussis antigen is contraindicated:

1. Allergic hypersensitivity.
2. Fever of 40.5 °C (105 °F) or greater within 48 hours.
3. Collapse or shocklike state (hypotonic-hyporesponsive episode) within 48 hours.
4. Persisting, inconsolable crying lasting three hours or longer or an unusual, high-pitched cry occurring within 48 hours.
5. Convulsion(s) with or without fever occurring within three days. (All children with convulsions, especially those with convulsions occurring within seven days of receipt of DTP, should be fully evaluated to clarify their medical and neurologic status before a decision is made on initiating or continuing vaccination with DTP [see next section, item 3]).
6. Encephalopathy occurring with seven days; this includes severe alterations in consciousness with generalized or focal neurologic signs. (A small but significantly increased risk of encephalopathy has been shown only within the three-day period following DTP receipt. However, most authorities believe that an encephalopathy occurring within seven days of DTP should be considered a contraindication to further doses of DTP.)

Immunization of infants and young children who have underlying neurologic disorders.—The presence of a neurologic condition characterized by changing developmental or neurologic findings, regardless of whether a definitive diagnosis has been made, is also considered a contraindication to receipt of pertussis vaccine, because administration of DTP may coincide with or possibly even aggravate manifestations of the disease. Such disorders include uncontrolled epilepsy, infantile spasms, and progressive encephalopathy. Stable conditions, such as cerebral palsy and developmental delay, are not considered contraindications to receipt of pertussis vaccination.

Although there are uncertainties in the reported studies, recent data suggest that infants and young children who have had previous convulsions (whether febrile or afebrile) are more likely to have seizures following DTP receipt than those without such histories.[illegible] A convulsion within three days of DTP receipt in a child with a history of convulsion(s) may be initiated by fever caused by the vaccine in a child prone to febrile convulsions, induced by the pertussis component, or unrelated to the vaccination. Available data do not indicate that seizures alone, temporally associated with DTP administration, induce permanent brain damage in these children.

Whether to administer DTP to children with proven or suspected underlying neurologic disorders, and when, must be decided on an individual basis. An important consideration is the current low frequency of pertussis reported in most areas of the United States, indicating a relatively low risk of exposure. Other considerations include the current near absence of diphtheria in the United States and the low risk that an infant will acquire an infection with *C tetani*. Based on these considerations and the nature of the child's disorder, the following approaches are recommended:

1. Infants as yet unimmunized who are suspected of having underlying neurologic disease. Possible latent central nervous system disorders that are suspected because of perinatal complications or other phenom-

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ena may become evident as they evolve over time. Because DTP administration may coincide with onset of overt manifestations of such disorders and result in confusion about causation, it is prudent to delay initiation of immunization with DTP or DT (but not OPV) until further observation and study have clarified the child's neurologic status. In addition, the effect of treatment, if any, can be assessed. The decision whether to commence immunization with DTP or DT should be made no later than the child's first birthday. In making this decision, it should be recognized that children with severe neurologic disorders may be at enhanced risk of exposure to pertussis from institutionalization or from attendance at clinics and special schools in which many of the children may be unimmunized. In addition, because of neurologic handicaps, these children may be in greater jeopardy from complications of the disease.

2. Infants and children with neurologic events temporally associated with DTP. Infants and children who experience a seizure within three days of receipt of DTP or an encephalopathy within seven days should not receive further pertussis vaccine, even though cause and effect may not be established (see "Precautions and Contraindications").

3. Incompletely immunized children with neurologic events occurring between doses. Infants and children who have received one or more doses of DTP and who experience a neurologic disorder, for example, a seizure, temporally unassociated with the administration of vaccine but before the next scheduled dose, present a special problem. If the seizure or other disorder occurs before the first birthday and completion of the first three doses of the primary series of DTP, deferral of further doses of DTP or DT (but not OPV) is recommended until the infant's status has been clarified. The decision whether to use DTP or DT to complete the series should be made no later than the child's first birthday and should take into consideration the nature of the child's problem and the benefits and risks of the vaccine. If the seizure or other disorder occurs after the first birthday, the child's neurologic status should be evaluated to ensure the disorder is stable before a subsequent dose of DTP is given (see next section).

4. Infants and children with stable neurologic conditions. Infants and children with stable neurologic conditions, including well-controlled seizures, may be vaccinated. The occurrence of single seizures (temporally unassociated with DTP) in infants and young children, while necessitating evaluation, need not contraindicate DTP immunization, particularly if the seizures can be satisfactorily explained. Anticonvulsant prophylaxis should be considered when giving DTP to such children. Parents of infants and children with histories of convulsions should be made aware of the slightly increased chance of postimmunization seizures.

5. Children with resolved or corrected neurologic disorders. Administration of DTP is recommended for infants with certain neurologic problems that have clearly subsided without residua or have been corrected, such as neonatal hypocalcemic tetany or hydrocephalus (following placement of a shunt and without seizures).

Immunization of infants and young children with family histories of convulsion or other central nervous system disorders. The ACIP, after evaluating the evidence available concerning the risk of a neurologic illness following pertussis vaccination of a child with a family history of convulsion or other central nervous system disorder, does not believe that such a history is a contraindication to pertussis vaccination.

Preparations Containing Diphtheria Toxoid and Tetanus Toxoid

The only contraindication to tetanus and diphtheria toxoids is a history of a neurologic or severe hypersensitivity reaction following a previous dose. Immunization with tetanus and diphtheria toxoids is not known to be associated with an increased risk of convulsions. Local side effects alone do not preclude continued use. If an anaphylactic reaction to a previous dose of tetanus toxoid is suspected, intradermal skin testing with appropriately diluted tetanus toxoid may be useful before a decision is made to discontinue tetanus toxoid immunization.[17] In one study, 94 of 95 persons giving histories of anaphylactic symptoms following a previous tetanus toxoid dose were nonreactive following intradermal testing and tolerated a further tetanus toxoid challenge without a reaction.[17] One person had immediate erythema and induration following skin testing but tolerated a full intramuscular dose without adverse effects. Mild, nonspecific skin-test reactivity to tetanus toxoid, particularly if used undiluted, appears to be fairly common. Most vaccinees develop inconsequential cutaneous delayed hypersensitivity to the toxoid.

Persons who experienced Arthus-type hypersensitivity reactions or fever greater than 39.4 °C (103 °F) following a prior dose of tetanus toxoid usually have very high serum tetanus antitoxin levels and should not be given even emergency doses of Td more frequently than every ten years, even if they have a wound that is neither clean nor minor.

If a contraindication to using tetanus toxoid-containing preparations exists in a person who has not completed a primary immunizing course of tetanus toxoid and other than a clean, minor wound is sustained, *only* passive immunization should be given using tetanus immune globulin (TIG) (see "Tetanus Prophylaxis in Wound Management").

Table 4 —Summary guide to tetanus prophylaxis in routine wound management—United States, 1985[*]

History of adsorbed tetanus toxoid (doses)	Clean, minor wounds		All other wounds[†]	
	Td[§]	TIG	Td[§]	TIG
Unknown or <3	Yes	No	Yes	Yes
≥3[¶]	No[**]	No	No[††]	No

[*] Important details are in the text.

[†] Such as, but not limited to, wounds contaminated with dirt, feces, soil, saliva, etc; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns and frostbite.

[§] For children under 7 years old, DTP (DT, if pertussis vaccine is contraindicated) is preferred to tetanus toxoid alone. For persons 7 years old and older, Td is preferred to tetanus toxoid alone.

[¶] If only three doses of *fluid* toxoid have been received, a fourth dose of toxoid, preferably an adsorbed toxoid, should be given.

[**] Yes, if more than 10 years since last dose.

[††] Yes, if more than five years since last dose. (More frequent boosters are not needed and can accentuate side effects.)

Although there is no evidence that tetanus and diphtheria toxoids are teratogenic, waiting until the second trimester of pregnancy to administer Td is a reasonable precaution to minimize any theoretical concern.

Diphtheria Prophylaxis for Case Contacts

All close contacts, household and other, with less than three doses of diphtheria toxoid should receive an immediate dose of a diphtheria toxoid-containing preparation and should complete the series according to schedule (see tables 1 and 2 [*JAMA* 1985; 254:897,900]). Close contacts who have had three or more doses who have not received a dose of a preparation containing diphtheria toxoid within the previous five years should receive a booster dose of a diphtheria toxoid-containing preparation appropriate for their age.

All close contacts should be examined daily for seven days for evidence of disease. Asymptomatic unimmunized or inadequately immunized close contacts should receive prompt chemoprophylaxis with either an IM injection of benzathine penicillin (600,000 units for persons younger than 6 years old and 1,200,000 units for those 6 years old or older) or a seven- to ten-day course of oral erythromycin (children: 40 mg/kg/day; adults: 1 g/day). Erythromycin may be slightly more effective, but IM benzathine penicillin may be preferred, since it avoids possible problems of noncompliance with a multiday oral drug regimen. Bacteriologic cultures before and after antibiotic prophylaxis may be useful in the follow-up and management of contacts. Identified untreated carriers of toxigenic *C diphtheriae* should receive antibiotics as recommended above for unimmunized household contacts. Those who continue to harbor the organism after either penicillin or erythromycin should receive an additional ten-day course of oral erythromycin.

Even when close surveillance of unimmunized close contacts is impossible, the use of equine diphtheria antitoxin is not generally recommended because of the risks of allergic reaction to horse serum. Immediate hypersensitivity reactions occur in about 7%, and serum sickness, in 5% of adults receiving the recommended prophylactic dose of equine antitoxin. The risk of adverse reactions to equine antitoxin must be weighed against the small risk of diphtheria occurring in an unimmunized household contact who receives chemoprophylaxis. If antitoxin is to be used, the usually recommended dose is 5,000 to 10,000 units IM—after appropriate testing for sensitivity—at a site different from that of toxoid injection. The immune response to simultaneous diphtheria antitoxin and toxoid innoculation is unlikely to be impaired, but this has not been adequately studied.

Cases of cutaneous diphtheria generally are caused by infections with nontoxigenic strains of *C diphtheriae*. However, a lesion suspected of being cutaneous diphtheria should be considered to be caused by a toxigenic strain until proven otherwise. Recommendations for prophylaxis of close case contacts are the same as for respiratory diphtheria, since cutaneous diphtheria may be more contagious than respiratory infection for close contacts. If a cutaneous case is known to be due to a nontoxigenic strain, routine investigation or prophylaxis of contacts is not necessary.

Tetanus Prophylaxis in Wound Management

Chemoprophylaxis against tetanus is neither practical nor useful in managing wounds; wound cleaning, debridement when indicated, and proper immunization are important. The need for tetanus toxoid (active immunization), with or without tetanus immune globulin (TIG) (passive immunization), depends on both the condition of the wound and the patient's immunization history (Table 4; see also "Precautions and Contraindications"). Rarely has tetanus occurred among persons with a documented primary series of toxoid injections.

A thorough attempt must be made to determine whether a patient has completed primary immunization. Patients with unknown or uncertain previous immunization histories should be considered to have had no previous tetanus toxoid doses. Persons who had military service since 1941 can be considered to have received at least one dose; although most may have completed a primary series of tetanus toxoid, this cannot be assumed for each person. Patients who have not completed a primary series may require

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tetanus toxoid and passive immunization at the time of wound cleaning and debridement (Table 4).

Available evidence indicates that complete primary immunization with tetanus toxoid provides long-lasting protection—ten years or more in most recipients. Consequently, after complete primary tetanus immunization, boosters—even for wound management—need to be given only every ten years when wounds are minor and uncontaminated. For other wounds, a booster is appropriate if the patient has not received tetanus toxoid within the preceding five years. Antitoxin antibodies develop rapidly in persons who have previously received at least two doses of tetanus toxoid.

Td is the preferred preparation for active tetanus immunization in wound management of patients 7 years old or older. This is to enhance diphtheria protection, since a large proportion of adults are susceptible. Thus, by taking advantage of acute health care visits, such as for wound management, some patients can be protected who otherwise would remain susceptible. For routine wound management of children younger than 7 years old who are not adequately immunized, DTP should be used instead of single-antigen tetanus toxoid. If pertussis vaccine is contraindicated or circumstances are such that potential febrile reactions following DTP might confound the management of the patient, DT may be used. For inadequately immunized patients of all ages, completion of primary vaccination at the time of discharge or at follow-up visits should be ensured (see tables 1 and 2 [*JAMA* 1985;254:897, 900]).

If passive immunization is needed, human TIG is the product of choice. It provides longer protection than antitoxin of animal origin and causes few adverse reactions. The currently recommended prophylactic dose of TIG for wounds of average severity is 250 units IM. When tetanus toxoid and TIG are given concurrently, separate syringes and separate sites should be used. The ACIP recommends the use of only adsorbed toxoid in this situation.

Pertussis Prophylaxis for Case Contacts

Spread of pertussis can be limited by decreasing infectivity of the patient and by protecting close contacts of that patient. To reduce infectivity as quickly as possible, a course of oral erythromycin (children: 40 mg/kg/day, adults: 1 g/day) or trimethroprim/sulfamethoxazole (children: trimethoprim 8 mg/kg/day, sulfamethoxazole 40 mg/kg/day; adults: trimethoprim 320 mg/day, sulfamethoxazole 1,600 mg/day) is recommended for patients with clinical pertussis. The antibiotic should be administered for 14 days to minimize any chance of antibiotic failure. Chemotherapy, however, probably does not affect the duration or severity of disease.

There are two approaches for protecting close contacts (such as children exposed in a household or day-care center) of patients with pertussis—active immunization and chemoprophylaxis. Close contacts younger than 7 years old who have not completed the four-dose primary series of DTP injections or who have not received a dose of DTP within three years of exposure should be given a dose of vaccine and should complete a primary series with the minimal intervals (see Table 1 [*JAMA* 1985;254:897, 900]). While the usefulness of chemoprophylaxis has not been well demonstrated, it may be prudent to consider a 14-day course of erythromycin or trimethoprim/sulfamethoxazole for close contacts younger than 1 year old, regardless of immunization status, and for unimmunized close contacts younger than 7 years old.

Prophylactic postexposure passive immunization is not recommended. Studies have shown that use of human pertussis immune globulin neither prevents illness nor reduces its severity. This product is no longer available in the United States.

§Relative risk was estimated by odds ratio.

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Senator **Hawkins**. Dr. Walker.

Dr. **Walker**. Thank you, Madame Chairman.

I am Bailus Walker, Commissioner of Public Health for the Commonwealth of Massachusetts. I am here today as a member of the executive committee of the Association of State and Territorial Health Officials and representing their views.

Each State or territory usually reviews the advice of the Federal agencies and professional scientific organizations, and then determines policy. In a majority of States, there is a statutory linkage between school attendance and childhood immunizations.

States, of course, vary in the amount of vaccine that they purchase directly and in the Federal assistance that they receive, but the total direct investment by the States is substantial. More importantly, all States have recognized that the true spirit of preventive medicine and public health has never been illustrated better than by the childhood immunization programs. Serious and sometimes fatal diseases that occur in countries that have not had immunization programs, or who have allowed them to lapse, have been gratifyingly rare in the United States.

Now, in an era when parents are not reminded daily of the horrors of preventable diseases, such as whooping cough, thoughts of vaccine reactions might overtake insights about the benefits of immunization. Therefore, we believe that it is the responsibility of everyone concerned about public health to see that there is a complete understanding of the benefits and risks.

The availability of a humane, equitable and logical solution of indemnification for the rare and unforeseeable adverse reaction to immunization is also necessary.

We believe that S. 827, the National Childhood Compensation Act, which is currently pending before Congress, is a commendable initiative toward bringing this important subject forward for discussion.

Madame Chairman, let me comment on some general features that the final bill should contain.

Given the state of the art in vaccine manufacture, a very small number of children will suffer a serious adverse reaction, through no fault of the manufacturer or physician. The rare illness resulting from the use of the vaccine is the price sometimes that we must pay to protect the rest of society. For these children, there is a need for an effective alternative to the tort system.

Under the present system, not only are there long delays and great uncertainty about whether an award will be made, but only a fraction of the award reaches the claimant after legal fees. An administrative hearing and award system, as an alternative to the current tort system, would seem to be the most humane and effective way of providing compensation for such children and their families.

For a remedy to be equitable, it would, by definition, need to balance the needs of the affected individual against the costs to his or her neighbors who are all part of the immunization benefit-risk process.

If compensation is inadequate, the health care needs of the individual will not be met, and public attitudes toward immunization would be affected. If the awards are excessive, and especially if they remain unpredictable, the costs attributable to vaccines would continue to escalate and could jeopardize the ability of States to fund public programs that might be the sole recourse for children most in need of preventive health services.

To find a balance and to allow it to remain current, we support the concept that appropriate formulas for compensation be developed by an advisory commission rather than by being fixed within the statutory language itself.

For the remedy to be logical, it should be consistent with the scientific knowledge and the principles by which a compensable injury could be defined. There must be an exclusion of the myriad of conditions in children's growth and development that were known to exist long before vaccines were in general use. Examples of these are hemolytic anemia, juvenile diabetes, and hyperactivity, all of which are included in the current language of S. 827.

Establishment of appropriate definitions appears to require either an expert advisory board or an administrative staff capable of interpreting scientific information. This expert committee, or membership, would also be expected to define pre-existing conditions that would present contraindications to immunizations. Additionally, expert opinion should be gathered as to ways to ensure full and adequate disclosure of all pertinent medical evidence to the court.

In conclusion, I look forward to the day when improved vaccines will obviate much of the current concern. However, there will probably always be a need for an administrative mechanism of compensation. Now this is true because biological products will, on rare occasions, interact unforeseeably with individuals who have differing reactions from the averages.

In my own State of Massachusetts, we are committing resources to vaccine improvements in our Public Health Laboratory. Federal funding, however, must be strengthened to go hand-in-hand with efforts by commercial manufacturers, upon whom most of the Nation depends.

We must recognize that assurance of an adequate supply of excellent vaccine at a reasonable cost is a complex effort that involves all elements of society and Government.

The legislation before Congress now, S. 827, we believe, paves the way for a significant airing of the issues. And while the Association of State and Territorial Health Officers cannot support this bill in its present form, we are pleased to have had this opportunity to comment and offer the fundamental principles that we believe the ultimate bill should have.

Madame Chairman, thank you very much.

[The prepared statement of Dr. Walker and responses to questions submitted for the record follow:]

TESTIMONY BEFORE THE

U.S. SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

JULY 18, 1985

"CHILDHOOD IMMUNIZATION: PROBLEMS AND OPTIONS"

STATEMENT OF

BAILUS WALKER, JR., Ph.D., M.P.H.
COMMISSIONER OF PUBLIC HEALTH
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

ON BEHALF OF

THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
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MR. CHAIRMAN AND DISTINGUISHED MEMBERS OF THE COMMITTEE, MY NAME IS DR. BAILUS WALKER. I AM COMMISSIONER OF PUBLIC HEALTH FOR THE MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH, AND I AM HERE TODAY ON BEHALF OF THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS. THE ASSOCIATION CONSISTS OF THE SENIOR PUBLIC HEALTH OFFICIALS IN EACH JURISDICTION WITH OVERALL RESPONSIBILITY FOR CHILDHOOD IMMUNIZATION PROGRAMS.

EACH STATE OR TERRITORY REVIEWS THE ADVICE OF FEDERAL AGENCIES AND PROFESSIONAL SCIENTIFIC ORGANIZATIONS, AND THEN DETERMINES POLICY. IN THE MAJORITY OF STATES THERE IS A STATUTORY LINKAGE BETWEEN SCHOOL ATTENDANCE AND CHILDHOOD IMMUNIZATIONS. STATES VARY IN THE AMOUNT OF VACCINE PURCHASED DIRECTLY, AND IN FEDERAL ASSISTANCE RECEIVED, BUT THE TOTAL DIRECT INVESTMENT IS SUBSTANTIAL. MORE IMPORTANTLY, ALL HAVE RECOGNIZED THAT THE TRUE SPIRIT OF PREVENTIVE MEDICINE AND PUBLIC HEALTH HAS NEVER BEEN ILLUSTRATED BETTER THAN BY THE CHILDHOOD IMMUNIZATION PROGRAMS. SERIOUS AND SOMETIMES FATAL DISEASES THAT OCCUR IN COUNTRIES THAT HAVE NOT HAD IMMUNIZATION PROGRAMS, OR WHO HAVE ALLOWED THEM TO LAPSE, HAVE BEEN GRATIFYINGLY RARE IN THE UNITED STATES.

IN AN ERA WHEN PARENTS ARE NOT REMINDED DAILY OF THE HORRORS OF PREVENTABLE DISEASES SUCH AS WHOOPING COUGH, THOUGHTS OF VACCINE REACTIONS MIGHT OVERTAKE INSIGHTS ABOUT THE BENEFITS OF IMMUNIZATION. THEREFORE, IT IS THE RESPONSIBLITY OF EVERYONE CONCERNED ABOUT THE PUBLIC'S HEALTH TO SEE THAT THERE IS A COMPLETE UNDERSTANDING OF THE BENEFITS AND RISKS. WE MUST MAKE IT CLEAR THAT

THE INDIVIDUAL IS NOT EXPECTED TO BE IMMUNIZED SOLELY FOR THE GROUP INTERESTS OF SOCIETY BUT RATHER BECAUSE IT IS ALSO IN THE INDIVIDUAL'S INTEREST. THIS UNDERSTANDING IS THE CORNERSTONE UPON WHICH GOOD COMPLIANCE WITH IMMUNIZATION PROGRAMS IS BASED.

THE AVAILABILITY OF A HUMANE, EQUITABLE, AND LOGICAL SYSTEM OF INDEMNIFICATION FOR THE RARE AND UNFORSEEABLE ADVERSE REACTION TO IMMUNIZATION IS ALSO NECESSARY. S 827, THE NATIONAL CHILDHOOD-INJURY COMPENSATION ACT, WHICH IS CURRENTLY PENDING BEFORE CONGRESS, IS A COMMENDABLE INITIATIVE TOWARD BRINGING THIS IMPORTANT SUBJECT FORWARD FOR DISCUSSION. LET ME COMMENT ON THE GENERAL FEATURES THAT THE FINAL BILL SHOULD CONTAIN.

GIVEN THE STATE OF THE ART IN VACCINE MANUFACTURE, A VERY SMALL NUMBER OF CHILDREN WILL SUFFER A SERIOUS ADVERSE REACTION THROUGH NO FAULT OF THE MANUFACTURER OR PHYSICIAN. THE RARE ILLNESS RESULTING FROM USE OF THE VACCINE IS THE PRICE WHICH MUST BE PAID TO PROTECT THE REST OF SOCIETY. FOR THESE CHILDREN, THERE IS A NEED FOR AN EFFECTIVE ALTERNATIVE TO THE TORT SYSTEM. UNDER THE PRESENT SYSTEM, NOT ONLY ARE THERE LONG DELAYS AND GREAT UNCERTAINTIES ABOUT WHETHER AN AWARD WILL BE MADE, BUT ONLY A FRACTION OF THE AWARD REACHES THE CLAIMANT AFTER LEGAL FEES. AN ADMINISTRATIVE HEARING AND AWARD SYSTEM, AS AN ALTERNATIVE TO THE CURRENT TORT SYSTEM, WOULD SEEM TO BE THE MOST HUMANE AND EFFECTIVE WAY OF PROVIDING COMPENSATION FOR SUCH CHILDREN AND THEIR FAMILIES.

FOR A REMEDY TO BE EQUITABLE, IT WOULD BY DEFINITION NEED TO BALANCE THE NEEDS OF THE AFFECTED INDIVIDUAL AGAINST THE COSTS TO

HIS/HER NEIGHBORS WHO ARE ALL PART OF THE IMMUNIZATION BENEFIT/RISK PROCESS. IF COMPENSATION IS INADEQUATE, THE HEALTH CARE NEEDS OF THE INDIVIDUAL WOULD NOT BE MET AND PUBLIC ATTITUDES TOWARD IMMUNIZATION WOULD BE AFFECTED. IF THE AWARDS ARE EXCESSIVE, AND ESPECIALLY IF THEY REMAIN UNPREDICTABLE, THE COSTS ATTRIBUTABLE TO VACCINES WOULD CONTINUE TO ESCALATE AND COULD JEOPARDIZE THE ABILITY OF STATES TO FUND PUBLIC PROGRAMS THAT MIGHT BE THE SOLE RECOURSE FOR CHILDREN MOST IN NEED OF PREVENTIVE HEALTH SERVICES. TO FIND A BALANCE, AND TO ALLOW IT TO REMAIN CURRENT, I SUPPORT THE CONCEPT THAT APPROPRIATE FORMULAS FOR COMPENSATION BE DEVELOPED BY AN ADVISORY COMMISSION RATHER THAN BY BEING FIXED WITHIN THE STATUTORY LANGUAGE ITSELF.

FOR THE REMEDY TO BE LOGICAL, IT SHOULD BE CONSISTENT WITH THE SCIENTIFIC KNOWLEDGE AND PRINCIPLES BY WHICH A COMPENSABLE INJURY COULD BE DEFINED. THERE MUST BE AN EXCLUSION OF THE MYRIAD CONDITIONS IN CHILDRENS' GROWTH AND DEVELOPMENT THAT WERE KNOWN TO EXIST LONG BEFORE VACCINES WERE IN GENERAL USE. EXAMPLES OF THESE ARE HEMOLYTIC ANEMIA, JUVENILE DIABETES, AND HYPERACTIVITY, ALL OF WHICH ARE INCLUDED IN THE CURRENT LANGUAGE OF S 827. ESTABLISHMENT OF APPROPRIATE DEFINITIONS APPEARS TO REQUIRE EITHER AN EXPERT ADVISORY BOARD OR AN ADMINISTRATIVE STAFF CAPABLE OF INTERPRETING SCIENTIFIC INFORMATION. THIS EXPERT COMMITTEE OR MEMBERSHIP WOULD ALSO BE EXPECTED TO DEFINE PRE-EXISTING CONDITIONS THAT WOULD PRESENT CONTRAINDICATIONS TO IMMUNIZATION. ADDITIONALLY, EXPERT OPINION SHOULD BE GATHERED AS TO WAYS TO INSURE FULL AND ADEQUATE DISCLOSURE OF ALL PERTINENT MEDICAL EVIDENCE TO THE COURT.

IN CONCLUSION, I LOOK FORWARD TO THE DAY WHEN IMPROVED VACCINES WILL OBVIATE MUCH OF THE CURRENT CONCERN. HOWEVER, THERE WILL PROBABLY ALWAYS BE A NEED FOR AN ADMINSTRATIVE MECHANISM OF COMPENSATION. THIS IS TRUE BECAUSE BIOLOGIC PRODUCTS WILL, ON RARE OCCASIONS, INTERACT UNFORSEEABLY WITH INDIVIDUALS WHO HAVE DIFFERING REACTIONS FROM THE AVERAGES.

IN MY OWN STATE OF MASSACHUSETTS WE ARE COMMITTING RESOURCES TO VACCINE IMPROVEMENTS IN OUR PUBLIC HEALTH LABORATORIES. FEDERAL FUNDING, HOWEVER, MUST BE STRENGTHENED TO GO HAND IN HAND WITH EFFORTS BY COMMERCIAL MANUFACTURERS UPON WHOM MOST OF THE NATION DEPENDS. WE MUST ALL RECOGNIZE THAT ASSURANCES OF AN ADEQUATE SUPPLY OF EXCELLENT VACCINE AT A REASONABLE COST IS A COMPLEX EFFORT THAT INVOLVES ALL ASPECTS OF SOCIETY AND GOVERNMENTS. THE LEGISLATION BEFORE THE CONGRESS NOW, S 827, PAVES THE WAY FOR A SIGNIFICANT AIRING OF THE ISSUES. WHILE THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS CANNOT SUPPORT THIS BILL IN ITS PRESENT FORM, I AM PLEASED TO HAVE HAD THE OPPORTUNITY TO COMMENT UPON THE ELEMENTS WHICH COULD BE AMENDED TO PROVIDE THE HUMANE, EQUITABLE, AND LOGICAL REMEDY NEEDED.

THANK YOU.

The Commonwealth of Massachusetts
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BAILUS WALKER, Jr. Ph.D. M.P.H.
Commissioner

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August 21, 1985

Honorable Orrin G. Hatch
Chairman, Committee
on Labor and Human Resources
United States Senate
Washington, D.C. 20510

Enclosed in response to your request for additional comment on the July 18 hearing on DTP vaccine and childhood immunization are answers to questions about how the Massachusetts Department of Public Health and our Commonwealth are currently dealing with these issues.

For additional information your staff should feel free to communicate with Dr. George R. Siber, Director of our Biologic Laboratories, or Dr. George F. Grady, Director our State Laboratory Institute. Both are reachable at telephone number (617) 522-3700, 305 South Street, Jamaica Plain, MA 02130.

Thank you again for the opportunity to testify on this important subject.

Sincerely,

Bailus Walker

Bailus Walker, Jr., Ph.D., M.P.H.
Commissioner

BW:M

QUESTIONS & RESPONSES FOR DR. WALKER

QUESTION #1 Has your State been named in any DTP lawsuits? How many? How are you handling this?

RESPONSE #1: The Commonwealth is currently in the process of litigating four tort actions at the Superior Court level involving the manufacture and distribution of DTP vaccine. Such claims are brought under the State Torts Claims Act, Massachusetts General Law, Chapter 258. This statute permits the state to be sued in tort for personal injuries or death caused by the negligent acts or omissions of a state employee acting within the scope of his or her employment. The statute provides that the remedy is to be exclusive and that the judgment shall not exceed $100,000 per claim. A claim may not be based on the performance of or failure to perform a discretionary duty.

As part of the tort claim process established under the statute, the state is given a six month period in which to evaluate the claim and seek a settlement or compromise where appropriate. At this point, the state has chosen to litigate the claims because of unresolved legal questions as to whether the Tort Claims Act is applicable in this situation, the Department's belief that it has not breached any standard of care in the manufacture and distribution of the vaccine, and the Department's view that the claims presented do not clearly establish a causal relationship between the vaccine and the injury to the child.

QUESTION #2: Do you believe that we now have the safest possible pertussis vaccine on the market?

RESPONSE #2:

- The current vaccine is a whole cell vaccine which contains a large number of substances found in pertussis bacteria. It is likely that as a result of continuing research, some of these substances may be found not to be essential for vaccine effectiveness and may contribute to toxicity. Thus it appears desirable and possible to develop a safer vaccine. However, I would urge that very careful studies be done to demonstrate that new candidate vaccines containing only a small number of protective substances are not only safer but as effective as our current whole cell vaccine. I would not view the demonstration that a new vaccine is better than no immunization as sufficient information to recommend adopting the new vaccine for general use in the U.S.

QUESTION #3: What are the long-term implications for States of increases in vaccine prices?

&

QUESTION #6: What is your evaluation of how the surcharge aspects of S.287 would affect the immunization programs?

RESPONSE #3 & #6: A fundamental requirement for preventive medical interventions is that they be affordable. This is especially true for immunizations, where virtually 100% participation is needed in order to achieve maximal disease prevention that results from "herd immunity". Recognition of this

RESPONSE #3 & #6-Cont'd: fact and recognition that the whole population benefits from immunization programs has prompted Massachusetts and other States to distribute childhood vaccines free-of-charge to its citizens. Rising vaccine prices (or rising costs of surcharges for the vaccines we manufacture ourselves) would impair our ability to provide vaccines at no charge. It is probable that a decrease in immunization rates and an increase in disease rate would result because many groups of children would be unable to afford the immunization. The groups of greatest concern would be the near-poor who are not covered either by private health insurance or by public assistance programs.

QUESTION #4: Can you foresee a day when the responsibility for producing and distributing vaccines will fall entirely on the Federal and State governments? Will you please comment on this?

RESPONSE #4: Yes, if the costs of liability coverage become excessive and/or totally unpredictable, it is possible that commercial manufacturers will elect to withdraw from the vaccine market. This would be an extremely undesirable development for many reasons. An important factor is that the expertise and capacity to develop, manufacture and test vaccines is so critical that it should not rest with a single facility such as a federally sponsored plant (or a single commercial

RESPONSE #4-Cont'd: manufacturer). The importance of having multiple manufacturers was vividly illustrated by the recent shortages of DTP vaccine. This is one of the reasons why two States, Massachusetts and Michigan, have elected to make certain of their vital vaccines themselves. Although this effort has proven to be foresighted and the operation of these existing facilities is certainly cost-effective, I do not believe that it is realistic or economically feasible that each State set up its own Biological Manufacturing Laboratory.

QUESTION #5: Please comment on the information and reporting requirements of S. 827 (especially sections 2141, 2143, and 2145).

RESPONSE #5: The physicians' reporting requirements described in Section 2141 of S.827 would be extremely onerous if they were mandated universally. For example, reporting of all deaths occurring within one (1) month of vaccine administration would require the reporting of approximately half of all deaths from all causes occurring in the U.S. between two and seven months of age. This would be true because 3 routine immunizations are given during this period. Section 2141 does not specify how the masses of information generated are to be evaluated. If the purpose is to ascertain the frequency of certain side effects after immunization, then carefully designed and controlled

RESPONSE #5-Cont'd: studies on smaller populations are more appropriate. Such studies are mandated already in Section 2142 "Study of Risks".

The manufacturer's record-keeping requirements in Section 2145 are already mandated by the Code of Federal Regulations. Currently these detailed manufacturing records are available for review by Federal inspectors at any time. A summary is submitted to the FDA prior to release of each vaccine lot. Mandatory submission of all manufacturing records would certainly impose a substantial burden on our Laboratories in Massachusetts and, most likely, an even greater burden on the Office of Biologics Research and Review of the FDA.

QUESTION #7: How many states manufacture their own vaccines? What is their legal exposure with respect to liability claims? Are they insulated from the liability problem which plagues the private manufacturers?

RESPONSE #7: There are only two states, Massachusetts and Michigan, which manufacture their own DTP vaccine. With regard to Massachusetts, the state may be sued only in accordance with the provisions and limitations of Massachusetts General Laws, chapter 258, the State Torts Claim Act, as described in the response to Question 1. The statute

RESPONSE #7-Cont'd: establishes a limit on damages of $100,000 per claim, thereby providing the state with a degree of protection not available to commercial manufacturers.

We understand that currently, Michigan is also protected from liability when performing a statutorily authorized governmental function, including vaccine manufacture.

QUESTION #8: Is it correct that the State of Massachusetts produces its own vaccines? What has your state's experience been with respect to claims made against it by parties injured by vaccines it produces?

RESPONSE #8: Massachusetts manufactures its own DTP vaccine. Until approximately two years ago, when public attention first began to be focused on DTP vaccine, the Department had not been named in a lawsuit involving vaccines. At this point, there are four cases currently pending at the Superior Court level, none of which has progressed beyond the discovery stage.

The state's experience thus far demonstrates the need for fair and effective compensation system for children injured as a result of receiving a childhood vaccine. Since children are statutorily mandated to receive certain vaccines, it appears inevitable, given the current state of the art in vaccine manufacture, that a small number of children will suffer a lasting injury as a re-

RESPONSE #8-Cont'd:

sult of an adverse reaction to the vaccine. Since such injury may arise through no fault of the manufacturer or physician, and since litigation involves considerable delay and expense, it appears that tort law does not provide an adequate remedy for those who are injured as a result of an immunization program. Consequently, the Department believes that there is a pressing need to devise a mechanism for ensuring that children proven to be injured as a result of receiving a childhood vaccine receive fair compensation without undue delay or obstacles.

Our experience up to this point also indicates the need for a careful evaluation of all possible causes of a child's illness or injury. Since it is often extremely difficult to determine whether there is a causal relationship between the vaccine and an illness which arises in the days and weeks after receiving the vaccine, each case requires a painstaking, individualized examination of possible causes. Any compensation system which is adopted must ensure that the process used to determine eligibility for compensation provides for a thorough inquiry into the most probable cause of the child's illness. The current version of S827 does not ensure such a critical review.

Senator Hawkins. Thank you very much, Dr. Walker.

Dr. Nelson, the compensation proposal that the AMA Task Force recommended endorses the idea of a no-fault system for compensating those injured by adverse reactions to vaccine. Do you feel that this is a unique situation that justifies establishing a no-fault system?

Dr. Nelson. Yes, we do, Madame Chairman. We think, first of all, that we have good data on the number of expected claims based on injuries, because of two reasons: First, good studies have been done, using matched case studies in England where sizable numbers of the population have not been vaccinated; second, about half of the vaccines that are given in this country are given under conditions of mandatory reporting, because they are given in the public sector.

Our commission received information from a variety of sources that agreed there was a predictable number of vaccine injuries that should be compensated rationally and adequately. With appropriate time brackets relating to the onset of signs of injury—that is, the length of time between administration of vaccine and onset of signs of injury—a reasonable way of knowing those children who, indeed, have a bona fide injury and should be compensated could be established. That makes it unique.

Some of the other no-fault compensation systems that are being considered involve much less precision in determining who has a legitimate claim.

Senator Hawkins. In your opinion, would a physician's medical malpractice coverage be affected if they were liable for up to $1 million judgment for each vaccine case, even if no fault was alleged or proven?

Dr. Nelson. As to the whole issue of the number of suits against physicians and nurses who administer vaccine, and the basis on which those suits are being brought, it's hard for us to get good data.

We certainly are not in favor of any bill which would protect a physician when, indeed, he or she has been negligent, and the AMA draft bill would permit the Secretary to bring suit against physicians or nurses when they have been negligent. We aren't attempting to duck our responsibility.

The professional liability implications of the particular aspect of professional liability relating to vaccine administration, when mixed in with the whole universe of problems that are attendant to professional liability as a whole, I think would be a relatively small part of the big problem.

Senator Hawkins. Dr. Walker, is there concern among health officers that more and more children will be referred to health clinics for their immunizations, rather than receive them in private physicians' offices?

Dr. Walker. I think there is that concern. We have not experienced that in Massachusetts, but I believe one or two other States that are members of the Association of State and Territorial Health Officials have experienced that.

Senator Hawkins. What impact has the rising cost of vaccines had on the ability of states to purchase vaccines?

Dr. Walker. I think it has had a significant impact on the ability of States to purchase vaccines. While we in Massachusetts make our own, we have had much discussion with other States who have really felt the pinch of the increasing cost of vaccines and, to some extent, have had to limit the distribution of vaccine in those States.

Senator Hawkins. Dr. Smith, I want to start by thanking you for all your help and assistance in working with us on developing this bill, and commend you for your efforts to educate your membership regarding adverse reactions. Your printed materials are excellent, and I notice you supplied each member of the committee with a copy of those posters and warning pamphlets, and I appreciate that because it's probably their first exposure to that.

Because communication between the physician and the parent is so important, I know that your personal efforts as an officer and as a leader in your pediatrics organization play an important role in spotting children who should not be given the booster shots or even the original shot.

Will the table of compensable events rule out all reactions not directly attributable to the vaccine?

Dr. Smith. We would be hesitant to claim that it would rule out every false claim.

Let me start by saying that we cannot claim perfection in the system now in existence. Claims presented in the courts that clearly, in the judgment of experts, would not justify a settlement, nevertheless receive one. There are others that are presented that should have a settlement and are not awarded any sort of settlement. The present system is not perfect. We can't claim that the table of injuries would do a perfect job of sorting the claims, but we think it will do a much better job because of its very nature and the way that it is constructed. We think it will be possible to do a great deal better job than is being done at the present time.

Senator Hawkins. I want to thank all of you for your participation here today. We have compiled a very good record for further action on S. 827.

[Additional material supplied for the record follows:]

TESTIMONY TO THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES ON SENATE BILL 827, THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT OF 1985

My name is ANTHONY M. COLANTONI. I am an attorney from Chicago, Illinois and a member of Advocates For A Safe Vaccine. On behalf of the Advocates For A Safe Vaccine, I would like to thank the members of the Labor and Human Resources Committee for allowing us the opportuntity to present our thoughts and views concerning the childhood immunization program and S. 827, the National Childhood Vaccine Injury Compensation Act of 1985. The problems and questions surrounding the immunization program and the Diptheria-Tetanus-Pertussis Vaccine are many and varied. Discourse and action are urgently needed to protect the health and welfare of our youngest citizens. Trial lawyers traditionally have advocated for those segments of society who by themselves are unable to seek redress for societal wrongs. We take particular pride in being members of that group. It is in this spirit that we submit our Interim Report entitled DTP VACCINE for your consideration.*

This report is the combined effort of attorneys from seven lawfirms engaged throughout the country in litigation on behalf of vaccine damaged children and their families against drug manufactures and health care providers alike. It is the result, in large part, of our efforts in the discovery stage of litigation to examine records of vaccine manufacturers, to review literally thousands of articles which have been published on all aspects of the issue and to confer with experts in various areas of science and medicine. We urge that this report be considered as an answer to some questions which you may already have and as a breeding ground for new questions which must be raised.

This Interim Report proves that pertussis manufacturers knew long ago that their whole cell pertussis vaccine was reactogenic. It also shows that these same manufacturers had the ability to make a safer, less reactive product. The testimony of the various representatives at the hearings, however, has attempted to suggest otherwise. They would have you believe that they have consistently manufactured the best and safest vaccine possible. That is simply not true and it is thus evident that the issue of responsibility must be re-examined and re-emphasized. Please note that the following remarks are my personal views and do not necessarily reflect the position of the Advocates For A Safe Vaccine. There can be no doubt that the manufacturers of the current varieties of DTP vaccine are at fault in making a reactive vaccine which causes serious neurological injuries to infants and children. There can be no doubt that these manufacturers were aware of the reactogenicity of their products, the reasons for the reactions and the technology to substantially to reduce these reactions some twenty-five (25) to thirty (30) years ago. There can be no doubt that the same companies, for reasons which yet remain unknown, conducted inadequate studies, ignored laboratory findings, disregarded clinical reports and continued to manufacture a vaccine which knowingly caused injury rather than produce a safer product or warn an unsuspecting public and the medical profession of the nature and rate of reactions and possible alternatives. I say that there can be no doubt because I have seen the documents from the manufacturers of the DTP vaccine themselves. Their knowledge of the reactogenicity of their product, their awareness of the cause of the reactions and their ability to make a safer product is in black and white. All you need do is request that these companies provide you with these same records that I have seen and you too will know the full extent of their knowledge and culpability.

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*Due to printing limitations and in the interest of economy, the report was retained in the files of the Committee.

Consider the current posture of the vaccine manufacturers in their request of this Committee for relief from liability. To the one, these manufacturers have sat before you and have told you that they have done everything that could possibly be done to make a safe product. They have stated that the injuries are rare and that those that occur are unavoidable, and that these reactions are more likely the result of host response rather than the toxicity of their product. They have urged that they should not bear the burden of responsibility for these injuries because they have engaged in the public good in the manufacturing of these vaccines. However, a review of their own documents and of the literature clearly shows that their assertions and claims are in many instances half truths and in many more, outright falsehoods. Indeed, in 1962, representatives of all DTP vaccine manufacturers in the U.S. agreed that "(t)here is evidence . . . that some reactions are the result of an idiosyncrasy on the part of the patient, while the majority of reactions appear to be due directly to the toxicity of the vaccine injected". These same representatives also wrote that clinicians had recognized for thirty (30) years prior to 1962 that the pertussis vaccine could be responsible for severe reactions. Moreover, at least one company was producing a soluble pertussis vaccine consistantly in the laboratory as early as 1969 but for unknown reasons did not market the product. Yet, the manufacturers now come before this Committee and the American public and tell an entirely different story. Nothing has changed in the interim, however, except for more death and injury, an increased number of lawsuits and their realization that they can no longer avoid responsibility for their negligence and manufacture of an unreasonably dangerous product which causes injury.

These vaccine manufacturers have known for more than 20 years that the whole cell pertussis vaccine causes serious neurological reactions. They have known for years that it was more likely that the toxicity of the vaccine rather than a host response was responsible for these reactions. They have suspected the cause of these reactions all along and have had for years the technology to make a less toxic and less reactogenic soluble, fractionated cell or accellular vaccine and simply chose not to do so. Their memoranda and their correspondence all clearly demonstrate this.

There is something morally repugnant about an industry possessed of this knowledge which now comes forward and requests protection with claims of innocence. There is something morally repugnant about an industry which has reaped the commercial benefits of a market composed of consumers who have no choice and worse yet no knowledge, which now comes before you and blames trial lawyers and sympathetic juries for high awards of damages. This industry which has caused so much havoc by the production of an unsafe vaccine must not now be exonerated at the expense of its victims and an unknowing American public. The manufacturers must admit and accept liability for their careless acts and for the knowing manufacture of a defective vaccine. They must pay their fair share of damages generated by their conduct. To allow otherwise would be to demean the deaths and devastating injuries befallen unknown numbers of infants, to betray the trust and confidence of the public and to establish an unspeakable precedent whereby an industry is rewarded and protected for ignoring its moral and legal responsibilities. Do not allow these manufacturers to make unsubstantiated, false claims. Senator Hatch promised that he would not legislate in the dark. I respectfully suggest that the brightest light would be shed from the records of these companies. Demand that they be produced and see for yourselves.

I feel compelled to also comment on some other remarks generated by some representatives today. Dr. Mason's assertion that lawsuits are not based on improperly made products cannot be farther from the truth. I invite each and every member of this Committee to review the pleadings filed in lawsuits brought on behalf of these victims. You will see that these suits are based on a manufacturer's production and distribution of an unreasonably dangerous defective vaccine which contains injury producing toxins, on their negligence in producing the vaccine despite knowledge that it causes reactions and their ability to reduce the reactions, on their failure to advise consumers and health care providers of the real risks and on their failure to determine the true severity and incidence of reactions. In particular cases, you will see allegations that a manufacturer deviated from its own production standards in manufacturing the vaccine.

Further, consider the basis upon which the lawsuits are settled and won. Manufacturers make offers of settlements and juries return verdicts against them because the evidence fairly establishes that they either breached expressed or implied warranties, manufactured a defective product which caused injury or engaged in negligent conduct in the manufacture of that product which caused injury. The awards and settlements are large because the injuries are devastating. The only "development" which has resulted in increased numbers of lawsuits is the recent awareness of victims and lawyers alike that the manufacturers may be legally liable for damages. I suggest that discovery of facts rather than changes in the law has occasioned the rise in litigation.

On this point too, the statement by insurance industry representatives that all that need be done to recover damages in the courtroom is to prove manufacture of the vaccine and injury, is totally inaccurate. The burden of the plaintiff in vaccine cases, as in virtually all other cases sounding in tort, is to prove not only that the defendant manufactured the product, but also that the vaccine was defective or that the manufacturer engaged in negligent conduct and that the vaccine *caused* the plaintiff's injury. This is a far greater requirement for recovery than what was suggested. That victims are in fact obtaining recovery only serves to underscore the negligent nature of the conduct involved and the unreasonably dangerous condition of the vaccine itself.

It is interesting to note the current attempt by some parties to whitewash Wyeth Laboratories announcement that it was stopping manufacture of its DTP vaccine. It *did not* announce a withdrawal from or unwillingness to distribute its product. Loudly and clearly, on June 13, 1984, Wyeth announced to the world that it was *ceasing* production of its DTP vaccine. Yet, to no one's knowledge, save itself and Lederle Laboratories with whom it had a distribution agreement, Wyeth produced millions of doses of the vaccine in 1984 after that June announcement. It makes no difference whether Wyeth initially intended to cease production and later struck a deal with Lederle. For months we were all led to believe that there was only one U.S. manufacturer and that there was a critical shortge of the vaccine when these were simply not the facts! Was this an example of corporate miscommunication or an attempt to create false vaccine shortages to put pressure on Congress to legislate immunity? While those involved might certainly claim the former, I submit that their record of performance mandates that they are no longer entitled to the benefit of any doubt.

Any compensation scheme which prohibits or bars vaccine injured children and their families from pursuing traditional tort remedies should be flatly rejected. While our current system of civil litigation may at times be slow or costly, it is unique in its ability to shift the burden of the cost of injury off of the shoulders of innocent victims and onto those who are both responsible for the injury and best able to bear its costs. The push for such a radical change which would prevent an injured party from suing comes not from a shift in social or public policy but rather from the unwillingness of the vaccine manufacturers to accept the consequences of their conduct.

Further, removal of the threat of civil litigation will in turn remove the impetus for manufacturers to develop a better product and ensure continuation of the status quo. It is no coindence thay the recent surge in acellular pertussis vaccine research comes in the wake of large settlements and jury verdicts against vaccine manufacturers for injuries caused by their defective product. The records of this industry demonstrate that they sat idle for years until forced into action by successful claimants. To remove the threat of litigation now would be to allow them to slip back into their old habits, something which we can ill afford to do.

Much has been said about the benefits of our childhood immunization program and the DTP vaccine in particular. It would be foolhardy to not recognize that the declines in morbidity and mortality from the diseases of diptheria, tetanus and whooping cough have in some degree resulted from the efficacy of the vaccine. However, we cannot ignore justifiably the fact that perhaps thousands of injuries could have been avoided had the knowledge and capabilities of the vaccine industry been fully nourished, encouraged and implemented. I urge that this committee take appropriate steps to review the records and documents of pertussis vaccine manufacturers. I submit that such a review will offer invaluable insight into the nature and extent of DTP vaccine injuries. It will show us the failings of the vaccine manufacturers in which we had placed our trust and confidence and suggest methods to encourage and ensure their future best efforts. It will provide the necessary guidance so that any system of compensation will truly be an enlightened response to the needs of vaccine injured children and to the health and safety of generations of children to come.

July 23, 1985

Barbara Loe Fisher
Dissatisfied Parents Together
128 Branch Road
Vienna, Virginia 22180

Committee on Labor and
  Human Resources
United States Senate
Washington, D.C. 20510

Mr. Chairman, Senator Hawkins and Committee Members:

My son's severe reactions to his third and fourth DPT shots and the fact that he sustained permanent neurological damage is not recorded in CDC statistics. Therefore, I would like this written testimony to serve as a record of what happened to him in hopes that it will serve as an example of why S. 827 should be passed. Also, perhaps the telling of his story will help educate another parent or doctor about pertussis vaccine reactions or prevent another child from becoming multiply learning disabled.

In this regard, I am also attaching a statement and documents (including those obtained under the Freedom of Information Act from the FDA) which were released on July 17, 1985 in San Francisco, California by Kevin Geraghty, M.D., of Physicians for the Study of Pertussis Vaccines. This important statement by a group of physicians who have investigated the effects of the pertussis vaccine, particularly the ability of bioactive pertussis toxin to induce allergies as well as varying degrees of neurological damage, is related to what happened to my son.

Christian, who is now seven years old, was a very healthy and happy baby. Except for an apparent allergy to milk, he never had a cold, ear infection or respiratory infection in the first two years of his life. When he received his third DPT shot in Alexandria, Virginia at seven months of age in 1978, he reacted with a large, hard, red, hot lump at the site of the injection which stayed there for nearly three weeks. When I called the doctor's office, the nurse told me "It was a bad lot of DPT vaccine. Don't worry about it."

In addition to being a very healthy baby, Christian was very bright. He began saying words at seven months of age and was speaking in sentences at two years of age. By two-and-a-half years, he could recognize by sight the upper case alphabet and half of the lower case alphabet as well as numbers 1-10. And he had created a "naming game" with a deck of cards. He would sit on his knees at a table for 45 minutes at a time, flip over the cards, and name them correctly. One doctor thought he might be "gifted."

When he was two years and seven months old, Christian received his fourth DPT shot because it was a Virginia state requirement for enrollment into a neighborhood church pre-school program. Just three weeks earlier, Christian had spiked a fever at the beach and had vomiting and diarrhea which lasted for several days. Within a week he was back to his cheerful, bright self. When I took him in for his booster shot, the only remnant of his bout at the beach was occasional diarrhea. I told the nurse about the big lump Christian had on the third DPT shot and the fact that he still had occasional diarrhea from his illness at the beach but she said it didn't matter.

Within four hours of his DPT shot, Christian lapsed into what I now know was a state of unconsciousness. He was sitting in a chair in his room when he suddenly became pale, stared at me blankly, rolled his eyes back, dropped his head sideways to his shoulder and went into a deep sleep. I thought it was strange that he could have fallen asleep so quickly sitting up. I tried to arouse him so he would walk to his bed but he wouldn't wake up. I carried him to his bed and he slept deeply for about six hours, missing dinner. When he woke up he had violent greenish-black diarrhea that lasted throughout the night and for the next several weeks. I had never seen that kind of diarrhea.

In the following days and weeks, Christian became a different child. No longer happy and adaptable, he became emotionally fragile, hyperactive and unable to concentrate. He no longer knew the alphabet or his numbers. He would not look at a deck of cards. He had "staring spells", which I now know may have been petit mal episodes. He had constant diarrhea, otitis media, and upper respiratory infections. He developed into a classic "allergic" child with dark circles under his eyes, skin eruptions, sneezing fits and a constant runny nose. He stopped eating, became emaciated, and stopped growing. After deteriorating for seven months, he was finally admitted to Children's Hosptial for tests for cystic fibrosis, celiac disease, and other disorders. All tests came back negative. The specialists had no answers as to why my healthy, bright, happy child had turned into a sickly, distracted, unhappy child.

My husband and I kept asking, "What happened to Christian in the fall of 1980? What was it that changed him?" Since he was our first child and we didn't have other children to compare him with, we kept telling ourselves that it was just a stage, that he would outgrow it. It wasn't until I saw "DPT: Vaccine Roulette," helped to organize Dissatisfied Parents Together, and began researching the pertussis vaccine that I discovered what had happened to my son, a discovery that eventually led to my co-authoring the book DPT: A Shot in the Dark. in the past three years, I have talked to hundreds of parents who have described their children's vaccine damage and many have described symptoms and permanent damage matching Christians's.

Today, Christian is highly allergic and has multiple learning disabilities. He has recently undergone extensive educational and psychological testing which revealed that he sustained neurological damage to his autonomic nervous system. Although he retained a high I.Q., he has an auditory processing deficit, fine motor skill delay, dyslexia, and attention span deficit. He cannot concentrate, is having great difficulty learning to read and write, and cannot process certain kinds of information correctly. He is labeled "bright but learning disabled." He is often frustrated, depressed and angry because he cannot produce academically. He will enter a self-contained learning disabled classroom in the public school system this fall.

How many other parents of the nearly three million learning disabled children in this country could trace their childrens' learning disablities back to severe reactions to the DPT shot if they (1) understood the definition of a severe reaction and (2) understood that bioactive pertussis toxin can cause varying degrees of neurological damage ranging from severe retardation and seizure disorders to learning disabilities, allergies and hyperactivity? How many of these children will not attend college or successfully hold jobs? How many will be chronically depressed and become teenage suicide statistics because they look normal and are expected to compete but can't? Lucky because they did not die or become severely retarded from their pertussis vaccine reaction, they nevertheless pay a different price in a society that has no concern for the victims of its grossly mismanaged mass pertussis vaccination program.

We will never know what might have been for Christian had he not received that fourth DPT shot despite the severe local reaction to his third DPT shot, despite the fact he had been recently ill, despite the fact there is a strong history of severe allergies and immune system disorders on both sides of our family. I cannot go back to that day in 1980 when I didn't know any better and I let the nurse give my son that fourth DPT shot. I cannot give back to Christian what has been taken from him.

But I can work to pass S. 827, which will legally mandate that parents receive adequate information about reactions and contraindications prior to vaccination and require that all doctors report reactions. If S. 827 had been in effect while Christian was receiving his DPT shots, I would have known that the severe local reaction after his third DPT shot was a warning sign; that he should have had his fourth shot deferred because he was not completely recovered from his illness; that his "deep sleep" was a classic shock/collapse pertussis vaccine reaction; that his subsequent "staring spells" may have been petit mal episodes; that his mental, emotional and physical deterioration were signs of a mild encephalopathy; and that I should have immediately reported the reaction to my doctor and he in turn should have reported it to the Centers for Disease Control. How many more severe vaccine reactions and subtle neurological injuries are not immediately recognized by parents or doctors and therefore are never recorded? They are not factored into the

CDC's benefit-risk analysis for the pertussis vaccine.

The passage of S. 827 as it is presently written will give us a way to correctly measure the extent of the damage caused by vaccines. It will ultimately result in scientific truth rather than scientific guess-work. If properly implemented, it will begin to reform the vaccine system, redeem the shameful history of denial and neglect of vaccine injuries, and restore public confidence in national health programs. But this will only happen if Congress passes S. 827 without distorting its guiding spirit: the search for truth and the realization of justice.

If Congress takes away parents' right to freely access the court system and tries to define vaccine damage so narrowly that only a handful of the true vaccine victims are compensated, there will be a backlash among parents that will destroy, not restore, confidence in vaccination programs. Only a government afraid of the truth and with little confidence in its ability to insure the safety of vaccines and responsible vaccine administration would absolve vaccine manufacturers and doctors from any responsibility for vaccine injuries by passing an exclusive remedy compensation system or one that would unfairly limit liability in the court system.

If this does happen, parents will have little reason to trust the system, to trust that the government insures that the safest possible vaccines are being manufacturered, tested, monitored, and administered to their children. They will know that those who make and administer vaccines are not held accountable for their actions and therefore have no incentive to act responsibly. They will know that if their child does sustain vaccine damage, there is little hope of securing financial support either through the court system or through a restrictive federal compensation system. I and many other parents throughout America pray that Congress will not pass an unjust compensation bill but will act responsibly and pass S. 827.

I would like to especially thank you, Senator Hawkins, for your long-term commitment to and concern for the health of all our children, both those who have benefited from vaccination and those who have been the victims of vaccination. Thank you for allowing me to submit this testimony.

Sincerely,

Barbara Loe Fisher

Barbara Loe Fisher, Vice President
Dissatisfied Parents Together

EDITOR'S NOTE

Because of space considerations, the following additional material is being retained in the Committee files:

"Information from Lederle: Vaccination, Pertussis and the Public Health"
(addendum to the testimony of Mr. Robert Johnson)

"D.T.P. Vaccine Interim Report" by Advocates for a Safe Vaccine
(addendum to the testimony for the record of Mr. Anthony Colantoni)

"Press Conference Statement: Contaminated DPT Vaccine" by Physicians for Study of Pertussis Vaccines
(addendum to the testimony for the record of Mrs. Barbara Fisher)

Senator **HAWKINS**. The hearing is now adjourned.

[Whereupon, at 1:23 p. m., the hearing was concluded.]

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